

**Exhibit T**

**Redacted**

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

- - - - -  
Michelle Simha, as  
Trustee for the  
Next-of-Kin of Noah  
Leopold,

Plaintiff, Civil File No.  
24-CV-01097-JRT-DTS

vs.

Mayo Clinic,

Defendant.

- - - - -  
DEPOSITION OF MAURICIO VILLAVICENCIO

Volume I, Pages 1 - 153

August 14, 2024

(The following is the deposition of Mauricio Villavicencio, taken pursuant to Notice of Taking Deposition, via video, at Mayo Clinic, Legal Department, 100 Second Street SW, Rochester, Minnesota, commencing at approximately 1:15 p.m., August 14, 2024.)

## CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

	Page 2	Page 4
1	APPEARANCES: 2 On Behalf of the Plaintiff: 3 Brandon Thompson Bibeana Metsch-Garcia (via Zoom) 4 CIRESI CONLIN LLP 225 South Sixth Street 5 Suite 4600 Minneapolis, Minnesota 55402 6 On Behalf of the Defendant: 7 Andrew Brantingham 8 DORSEY & WHITNEY LLP 50 South Sixth Street 9 Suite 1500 Minneapolis, Minnesota 55402 10 ALSO PRESENT: 11 Ron Huber, Videographer 12 Anna C. Messerly, Ciresi Conlin Maggie Palmisano, Ciresi Conlin (via Zoom) 13 Sheri Peterson, Mayo Clinic Michelle Simha (via Zoom) 14 Norman Leopold (via Zoom) Karen Leopold (via Zoom) Jenna Shulman (via Zoom) 15 16 17 18 19 20 21 22 23 24 25	1 PROCEEDINGS 2 THE VIDEOGRAPHER: We're on the record. 3 Today is August 14th, 2024. The time is 1:15 4 p.m. Today's case caption is Simha versus Mayo 5 Clinic. The witness for today's deposition is 6 Mauricio Villavicencio. 7 At this time the court reporter will 8 swear the witness. 9 (Witness sworn.) 10 MR. BRANTINGHAM: Brandon, I'm sorry, 11 before you proceed, can I just -- 12 I just want to put on the record that I -- that I provided the emails to you -- 13 MR. THOMPSON: Oh, sure. 14 MR. BRANTINGHAM: -- that I believe 15 completes the production of responsive emails from Dr. Villavicencio. Obviously we'll talk 16 about anything about that further, I just wanted 17 to put it on the record -- 18 MR. THOMPSON: Sounds good. 19 MR. BRANTINGHAM: -- lest I forget when it happened. 20 MR. THOMPSON: Sounds good. 21 MR. BRANTINGHAM: Please proceed. 22 MAURICIO VILLAVICENCIO,
1	EXAMINATION INDEX 2 WITNESS EXAMINED BY PAGE 3 Dr. Villavicencio Mr. Thompson 5 4 Mr. Brantingham 125 5 Mr. Thompson 130 6 EXHIBIT INDEX 7 EXHIBIT DESCRIPTION PAGE 8 1 OPTN Guidance for Donor and 129 Recipient Information Sharing, Mayo_Leopold_0024837 to '4844 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	1 called as a witness, being first duly 2 sworn, was examined and testified as 3 follows: 4 EXAMINATION 5 BY MR. THOMPSON: 6 Q. All right. Doctor, have you ever had 7 your deposition taken before? 8 A. No. 9 Q. So just a couple of quick ground rules 10 to make sure that we get on the same page and we 11 get a nice, clean record. 12 Number one, try to keep your voice up. 13 You're a little bit of a soft talker so far. It 14 makes the court reporter's job easier if you can 15 speak as loudly as you can. Okay? 16 A. Sure. 17 Q. Let's try really hard not to talk over 18 one another. I'm bad about that, as we've 19 established over the course of the last few 20 days, but I'm going to try hard not to talk over 21 you and you try hard not to talk to over me. 22 Okay? 23 A. Sounds good. 24 Q. Verbal responses like yeses and nos are really good; shakes of the head and nods and

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<p style="text-align: center;">Page 6</p> <p>1      grunts or uh-huhs and huh-uhs are not good 2      because they're hard to take over on the 3      transcript. So make sure you respond verbally. 4      Okay?</p> <p>5      <b>A. Okay.</b></p> <p>6      Q. If any of my questions are in any way 7      unclear, will you promise to let me know so I 8      can rephrase my question and make sure you and I 9      are on the same page?</p> <p>10     <b>A. Sure.</b></p> <p>11     Q. All right. You're the director of the 12    heart/lung transplant program here at Mayo; is 13    that right?</p> <p>14     <b>A. Yes, sir.</b></p> <p>15     Q. Tell me a little bit about the 16    transplant program.</p> <p>17     <b>A. Well the lung transplant program has 18    been very successful in the recent years since I 19    came and we have achieve great results and we 20    have transplanted way more people than was 21    before maintaining excellent outcomes, so we're 22    kind of proud in terms of clinical experience 23    per year. We count the experience per year. 24    We're around 10th in the nation for volume.</b></p> <p>25     Q. For lungs or hearts?</p>	<p style="text-align: center;">Page 8</p> <p>1      What are the most important survival 2      metrics to you as the director of the program 3      here?</p> <p>4      <b>A. Ninety-day survival as in the surgical 5      side, but it matters to me most what happens in 6      the long run. For example, in the last 7      scientific registry of transplant recipients we 8      have the highest survival three year of follow- 9      up in the country.</b></p> <p>10     Q. Are you talking about for heart or 11    lung?</p> <p>12     <b>A. For heart.</b></p> <p>13     Q. Where does --</p> <p>14     When you say "we," are you talking just 15    about Rochester, or are you talking about 16    Jacksonville, Arizona, and Rochester together?</p> <p>17     <b>A. Rochester only.</b></p> <p>18     Q. All right. So where does Mayo 19    Rochester rank in terms of one-year survival 20    statistics for heart transplant?</p> <p>21     <b>A. Average in the nation.</b></p> <p>22     Q. Average.</p> <p>23     <b>A. Uh-huh.</b></p> <p>24     Q. Do you know why that is?</p> <p>25     <b>A. It's around 90 percent, 90, 92 percent</b></p>
<p style="text-align: center;">Page 7</p> <p>1      <b>A. For -- for both.</b></p> <p>2      Q. What year's statistic are you using 3      there that you're 10th in the nation in volume?</p> <p>4      <b>A. 2023, 2024. So I have managed to boost 5      the program since I arrived 2021. Before we 6      were like 40 in the nation, --</b></p> <p>7      Q. And there --</p> <p>8      <b>A. -- something like that.</b></p> <p>9      Q. I'm sorry.</p> <p>10     There again you're talking about 11    volume, number of transplants.</p> <p>12     <b>A. Number of transplant and outcomes.</b></p> <p>13     Q. So when a transplant program is being 14    evaluated, --</p> <p>15     <b>A. Uh-huh.</b></p> <p>16     Q. -- number of transplants is an 17    important metric and outcomes is an important 18    metric; right?</p> <p>19     <b>A. Yes, sir.</b></p> <p>20     Q. When we're talking about outcomes, 21    we're talking about the one-year survival 22    outcomes?</p> <p>23     <b>A. That's one of the metrics. There are 24    several metrics.</b></p> <p>25     Q. What is --</p>	<p style="text-align: center;">Page 9</p> <p>1      <b>at a year.</b></p> <p>2      Q. No. Sorry.</p> <p>3      Do you have an idea of why Mayo is just 4      average when it comes to one-year survival?</p> <p>5      <b>A. Because we have excellent outcomes, so, 6      you know, there's half of the country that's 7      below us.</b></p> <p>8      Q. Sure. But there's also half of the 9      country that's above you.</p> <p>10     <b>A. Yeah. But you could filter your 11    results to get them better and do low-risk 12    patients and not transplant anybody.</b></p> <p>13     Q. So with --</p> <p>14     <b>A. So it's excellent results, sir.</b></p> <p>15     Q. With respect to volume, when we talk 16    about volume being an important metric, we're 17    talking getting the volume numbers up. Right?</p> <p>18     <b>A. Yeah. So that people don't die from 19    heart failure.</b></p> <p>20     Q. Sure. Where does Mayo --</p> <p>21     You said 10th in the nation in volume?</p> <p>22     <b>A. Yes, sir.</b></p> <p>23     Q. Just for heart.</p> <p>24     <b>A. Yes.</b></p> <p>25     Q. And that's just --</p>

3 (Pages 6 to 9)

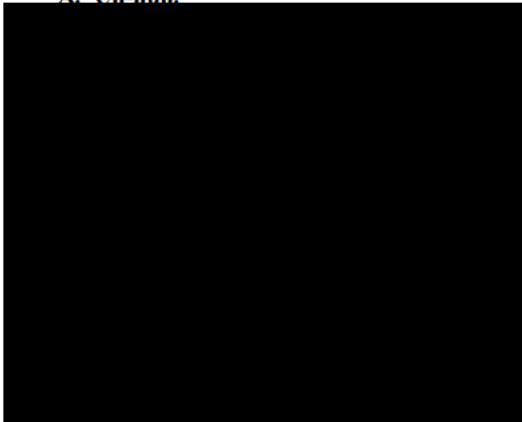
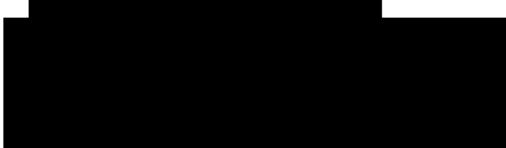
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<p style="text-align: center;">Page 10</p> <p>1       <b>A. Not for lung, too.</b>      2       Q. Let's stick just with heart. Okay?      3       <b>A. Okay.</b>      4       Q. I'm going to focus --      5       <b>A. I haven't say anything about lung, but you asked me.</b>      6       Q. I'm going to focus really specifically      7       on heart transplant --      8       <b>A. Uh-huh.</b>      9       Q. -- for purposes of our discussions      10      today.      11      So your testimony is that with respect      12      to the heart transplant program, Mayo Rochester      13      is 10th in the nation in volume.      14      <b>A. Correct.</b>      15      Q. Where was it when you started here when      16      you took over the program?      17      <b>A. Thirty, 40, somewhere in there.</b>      18      Q. I -- I assume that you're proud of the      19      fact that you've increased the numbers of      20      transplants?      21      <b>A. Yeah. Proud of the fact of saving lives by heart transplantation.</b>      22      Q. My question was: Are you proud of the      23      fact that Mayo's volume numbers have gone up?</p>	<p style="text-align: center;">Page 12</p> <p>1       Q. Was the EXPAND trial funded by      2       TransMedics?      3       <b>A. Yes.</b>      4       Q. Is that the only research study you've      5       been involved in that was funded by TransMedics?      6       <b>A. No, I -- I --</b>      7       <b>In heart -- we're talking about heart only again --</b>      8       Q. Yes.      9       A. -- on this case, so in the -- then      10      the -- the postmarket-approval registry is      11      funded and mandated by the FDA. I'm the      12      principal investigator here at the Mayo Clinic      13      for that.      14      Q. You're the principal investigator you      15      said?      16      <b>A. Yes.</b>      17      Q. How much money does TransMedics provide      18      to Mayo for that?      19      <b>A. I don't -- I don't know exactly. It's minimal enough to, you know, maintain the record.</b>      20      Q. More than a hundred thousand dollars?      21      <b>A. I don't know.</b>      22      Q. What other --</p>
<p style="text-align: center;">Page 11</p> <p>1       <b>A. I answered your question. I'm proud of the fact that when we increased the volume, save heart-failure patients from death.</b>      2       Q. Tell me about your involvement with TransMedics.      3       <b>A. I -- I start using TransMedics during the clinical trials at the Massachusetts General Hospital in Boston when I was a -- an attending heart transplant surgeon at the Mass General Hospital.</b>      4       Q. That was your first involvement with TransMedics?      5       <b>A. Yes. I'm not sure 2015, maybe the end of, because I started September 2015. For sure I would say in 2016, eight years ago.</b>      6       Q. And so back then your involvement with TransMedics was being involved in the PROCEED trial?      7       <b>A. No. I was the --</b>      8       <b>In the EXPAND trial. The PRO -- the PROCEED trial had already been done.</b>      9       Q. That's right. That was doctors mostly at UCLA?      10      <b>A. Yeah, UCLA, some people in Europe, Columbia.</b></p>	<p style="text-align: center;">Page 13</p> <p>1       You mentioned something about lung.      2       Have you had involvement with TransMedics for lung as well?      3       <b>A. Yeah. I participated in the EXPAND trial. So in the case in the Mass General I was the co-investigator -- co-investigator for the EXPAND trial, but in the -- the lung side I was the principal investigator for the EXPAND trial in -- for, you know, this, you know, FDA-regulated trial.</b>      4       Q. And so both of those were funded exclusively by TransMedics.      5       <b>A. Yes.</b>      6       Q. Have you ever met the CEO of TransMedics?      7       <b>A. Yes.</b>      8       Q. How many times?      9       <b>A. Several times.</b>      10      Q. More than ten?      11      <b>A. Probably. I don't know. I don't count how many times I meet people.</b>      12      Q. Okay.      13      <b>A. Maybe 30 times.</b>      14      Q. Thirty times.      15      <b>A. Maybe. I don't know. I don't count</b></p>

<p style="text-align: center;">Page 14</p> <p>1     <b>them. I'm guessing.</b>      2       Q. Have you ever traveled on a -- and had      3       that funded in any way by TransMedics?      4       <b>A. Yeah. I have traveled to the</b>      5       <b>investigative meetings I think twice.</b>      6       Q. Where were those meetings?      7       <b>A. One was in -- in Saint Thomas and one</b>      8       <b>was in Boston, not very long travel from home.</b>      9       Q. TransMedics funded a meeting in Saint      10      Thomas, the Virgin Islands?      11       <b>A. Yes, sir.</b>      12       Q. And paid for you to travel there?      13       <b>A. Yes.</b>      14       Q. Any --      15       <b>A. Oh, and there was one in the --</b>      16       <b>So there's two, that one and there's</b>      17       <b>one in -- I think they did one in the -- in</b>      18       <b>Nassau, I think in Bahamas.</b>      19       Q. In the Bahamas.      20       <b>A. Uh-huh.</b>      21       Q. Got it.      22       And TransMedics paid for you to go      23      there, too.      24       <b>A. Yes, sir.</b>      25       Q. Any other ways that TransMedics has</p>	<p style="text-align: center;">Page 16</p> <p>1       <b>Because I'm -- I didn't find it</b>      2       <b>interesting and I didn't have trip days.</b>      3       Q. Didn't have what?      4       <b>A. Trip days.</b>      5       Q. Trip days. Got it.      6       <b>A. So like the time that I can get out</b>      7       <b>of -- of the Mayo Clinic.</b>      8       Q. Yep. Got it.      9       When TransMedics flew you to the Virgin      10      Islands and the Bahamas, did they fly you first      11      class or coach?      12       <b>A. Coach.</b>      13       Q. You got to fix that for the next time.      14       Do you have stock in TransMedics?      15       <b>A. No.</b>      16       Q. Do you know -- well you --      17       I assume you know that one of the      18      things that the SRTR tracks is selectivity      19      statistics.      20       <b>A. No.</b>      21       Q. Are you aware of that?      22       <b>A. No.</b>      23       Q. Okay. So then I would assume that you      24      have no idea how Mayo Rochester matches up with      25      other institutions in terms of selectivity.</p>
<p style="text-align: center;">Page 15</p> <p>1       provided you with any sort of financial benefit?      2       <b>A. No, I have not receive any consulting</b>      3       <b>fees.</b>      4       Q. Do you have --      5       <b>A. Nothing other than travel and</b>      6       <b>accommodation for these two meetings and the</b>      7       <b>Boston one.</b>      8       Q. Where did you stay in Saint Thomas?      9       <b>A. I -- I stayed in the Ritz-Carlton in</b>      10      <b>Saint Thomas.</b>      11       Q. How about when you went to the Bahamas      12      on TransMedics' dime?      13       <b>A. What was it? Atlantis, I believe.</b>      14       Q. Both very nice places.      15       <b>A. Yeah. Been more than five years since</b>      16      <b>then.</b>      17       Q. Sure.      18       Any plans for TransMedics to have      19      meetings with these new studies that are going      20      on?      21       <b>A. I haven't heard any. There was --</b>      22       <b>There were meetings of the</b>      23       <b>investigators, I think, last year. I didn't go.</b>      24       Q. Why not?      25       <b>A. In Boston.</b></p>	<p style="text-align: center;">Page 17</p> <p>1       <b>A. What do you mean by "selectivity?" I</b>      2       <b>haven't heard about that term before in heart</b>      3       <b>transplantation.</b>      4       Q. Well so, for example, one of things      5      that SRTR tracks is offer-acceptance      6      characteristics. Do you know that?      7       <b>A. Oh, yeah. Yeah.</b>      8       Q. Yep.      9       <b>A. I wouldn't call that selectivity.</b>      10       Q. Well so do you know what the offer-      11      acceptance ratio refers to?      12       <b>A. Yeah. It was --</b>      13       <b>It's better than in the nation.</b>      14       Q. My question was: Do you know what the      15      offer-acceptance ratio is?      16       <b>A. I can't remember the number, --</b>      17       Q. No, no.      18       <b>A. -- but I just can remember our</b>      19       <b>relationship to the nation, that it was better</b>      20       <b>than, you know, the whole nation.</b>      21       Q. Well "better than," you mean that Mayo      22      accepts a lot more organs than other      23      institutions do?      24       <b>A. Yeah.</b>      25       Q. One of the things that I read in some</p>

<p style="text-align: right;">Page 18</p> <p>1 materials that were put out by Mayo is a quote 2 that says, "We say yes when others say no." 3 Have you heard that little catch phrase?</p> <p>4     <b>A. Yeah.</b></p> <p>5     Q. Do you believe in that catch phrase?</p> <p>6     <b>A. We try to do everything that is</b> 7     <b>medically possibly to improve the patients'</b> 8     <b>lives --</b></p> <p>9         Q. Uh-huh.</p> <p>10      <b>A. -- and save them from death.</b></p> <p>11      Q. Yeah. No, my question was just: Do 12 you subscribe to that little catch phrase, "We 13 say yes" --</p> <p>14      <b>A. Well it -- it --</b></p> <p>15      Q. You got to --</p> <p>16         Hold on. Hold on. Doctor, you got to 17 let me finish.</p> <p>18         MR. BRANTINGHAM: Yeah. Let him finish 19 the question after and then -- then you go.</p> <p>20         Q. Do you subscribe to that catch phrase, 21 "When other" -- I guess it's "When others say 22 no, we say yes?"</p> <p>23      <b>A. It's a slogan. I am not in the</b> 24      <b>Marketing Department.</b></p> <p>25      Q. Do you know where Mayo Rochester ranks</p>	<p style="text-align: right;">Page 20</p> <p>1 hearts with an ejection fraction below 60 as the 2 national average; right?</p> <p>3     <b>A. I don't know. I don't remember.</b></p> <p>4         Q. Okay. If I told you that the latest 5 statistics for SRTR was that Mayo took more than 6 three times as many hearts from donors over the 7 age of 40, does that sound about right to you?</p> <p>8         <b>A. Yes, sir.</b></p> <p>9         Q. And almost four times as many hard-to- 10 place hearts as the national average?</p> <p>11      <b>A. Yes.</b></p> <p>12         Q. And more than double the number of 13 donors from more than 500 miles away?</p> <p>14         <b>A. Yes.</b></p> <p>15         Q. Now in order to do that, --</p> <p>16         <b>A. Uh-huh.</b></p> <p>17         Q. -- you got to use the OCS; right?</p> <p>18         <b>A. Yeah. In part.</b></p> <p>19         Q. Well you can't go get a donor heart 20 from more than 500 miles away using just 21 standard cold cardioplegia; can you?</p> <p>22         <b>A. Well it depends because, you know,</b> 23         <b>other centers might choose to use another</b> 24         <b>preservation method, SherpaPak, for example, and</b> 25         <b>they -- I've heard about a report that the Mass</b></p>
<p style="text-align: right;">Page 19</p> <p>1 in terms of the ratio of taking high-risk 2 hearts?</p> <p>3     <b>A. You mean high-risk of -- in terms of</b> 4     <b>the Public Health Service?</b></p> <p>5         Q. Yes.</p> <p>6     <b>A. So in terms of risk of viral infection?</b></p> <p>7         Q. Yes.</p> <p>8     <b>A. I -- I think it's -- I --</b></p> <p>9         I'm not sure. You know, I don't have 10 the report on my side here, but I think it was 11 probably twice as in the country, something like 12 that. I can't remember. Maybe you have it 13 there.</p> <p>14         Q. Yeah. Two and a half times --</p> <p>15     <b>A. Yeah.</b></p> <p>16         Q. -- the national average in terms of --</p> <p>17     <b>A. Yeah.</b></p> <p>18         Q. -- taking hearts that are considered 19 high risk.</p> <p>20     <b>A. No. You are -- you are saying it</b> 21     <b>wrong. It's increased risk of viral</b> 22     <b>infections --</b></p> <p>23         Q. Increased risk. Got it.</p> <p>24     <b>A. -- by the Public Health Service.</b></p> <p>25         Q. Mayo takes more than twice as many</p>	<p style="text-align: right;">Page 21</p> <p>1     <b>General went to Alaska and got a heart from</b> 2     <b>Alaska with cold storage --</b></p> <p>3         Q. Huh.</p> <p>4         <b>A. -- with SherpaPak.</b></p> <p>5         Q. Does Mayo use the SherpaPak?</p> <p>6         <b>A. No. It was on the shelf, but I haven't</b> 7         <b>used it. I used it when I was in the Mass</b> 8         <b>General. I wasn't the director of the program</b> 9         <b>at that time.</b></p> <p>10         Q. Is there a different director of the 11 transplant program at Mayo Jacksonville?</p> <p>12         <b>A. Yes.</b></p> <p>13         Q. And a different one at Mayo Arizona?</p> <p>14         <b>A. Yes.</b></p> <p>15         Q. Do you know why the offer-acceptance 16 ratios at the other two Mayo institutions are so 17 much lower than Rochester's?</p> <p>18         <b>A. I don't --</b></p> <p>19         <b>In general terms, they -- you know,</b> 20         <b>it's just -- I'll put it on the general word --</b> 21         <b>probably they are more conservative.</b></p> <p>22         Q. Do you remember the Noah Leopold case?</p> <p>23         <b>A. Yes, sir.</b></p> <p>24         Q. Do you have like a lot of memories of 25 it or just a few?</p>

<p style="text-align: center;">Page 22</p> <p>1       <b>A. I have a lot of memories.</b>      2       Q. Do you consider the Noah Leopold case      3       to have been a failure?      4       <b>A. It's unfortunate that a patient would have die.</b>      5       Q. That wasn't my question though.      6       Do you consider the Noah Leopold case      7       to have been a failure?      8       <b>A. I -- I think it's unfortunate a patient would have die.</b>      9       Q. Is --      10      <b>A. If you want to quote it as failure, that's you -- what you say, not what I say.</b>      11      Q. No. I'm asking if you agree with it though.      12      <b>A. Then I don't agree with it.</b>      13      Q. Okay. You don't agree that it was a failure.      14      <b>A. No.</b>      15      Q. Do you agree that what happened to Noah Leopold was a catastrophe?      16      <b>A. I don't think so.</b>      17      Q. No?      18      You just think it was unfortunate.      19      <b>A. It was a tragedy and unfortunate.</b></p>	<p style="text-align: center;">Page 24</p> <p>1       <b>A. Yeah, I -- I think the -- this gentleman here next to me, Mr. --</b>      2       MR. BRANTINGHAM: Brantingham.      3       <b>A. -- Brantingham, I don't know how to pronounce it, --</b>      4       MR. BRANTINGHAM: Andrew's fine.      5       <b>A. -- you know, show me some.</b>      6       Q. Okay. Did you --      7       Have you seen the text messages that refer to either Dr. Altarabsheh or Dr. Knop telling you that the lactates for the donor heart for Noah Leopold were bad or terrible?      8       <b>A. No. I -- I -- I don't recall that. And if they say that, it's completely wrong because the lactates were excellent.</b>      9       Q. No. I understand that. That wasn't my question.      10      You know that there are a number of text messages that suggest that you asked Dr. Altarabsheh and/or Dr. Knop about the lactates and they gave you the impression that the lactates were not good; right?      11      <b>A. No.</b>      12      MR. BRANTINGHAM: Object to the form and foundation. I'm frankly not sure he is. I</p>
<p style="text-align: center;">Page 23</p> <p>1       Q. Okay. Do you remember talking with either Dr. Altarabsheh or Dr. Knop from the operating room?      2       <b>A. Do you mean when they were in the operating room with the donor?</b>      3       Q. Yeah. So let me ask it a little tighter way. There's some text messages sent in this case that --      4       <b>A. Uh-huh.</b>      5       Q. -- suggest that one --      6       You're aware of those text messages.      7       <b>A. What?</b>      8       Q. You're nod --      9       I started saying "text messages" and you nodded your head and said "uh-huh" like you're aware of what I'm talking about.      10      <b>A. No, I'm -- no, I'm --</b>      11      <b>People might have sent text messages.</b>      12      <b>I normally do not communicate like that.</b>      13      Q. Yeah.      14      <b>A. I'm Chilean, you know, I use very little text messaging.</b>      15      Q. Are you aware of the fact that there are a number of text messages that have been produced that are relevant to this case?</p>	<p style="text-align: center;">Page 25</p> <p>1       mean if you want to show him --      2       MR. THOMPSON: Yeah, he might not be.      3       That's fine.      4       <b>A. I --</b>      5       Q. Do you remember --      6       <b>A. I mean if somebody says that, it's wrong. I don't care.</b>      7       Q. Do you remember asking Michael Pick to go get the lactate values?      8       <b>A. I always ask the perfusionist the lactate values.</b>      9       Q. Okay. Do you remember anyone suggesting to you, before you saw the lactate values, that there was an issue with them?      10      <b>A. There was no one.</b>      11      Q. No one made such a suggestion to you.      12      <b>A. No. There was no bad lactic acid --</b>      13      Q. That wasn't my question.      14      <b>A. -- volume.</b>      15      Q. We'll talk about -- we'll talk about the lactates. I'm not asking whether there were bad lactates.      16      I'm going to show you Mayo 25074, first of all. Do you see that top text message?      17      Doctor, I'm asking you if you see the</p>

<p style="text-align: center;">Page 26</p> <p>1 top text message.      2       <b>A. Yeah, I see that, but I don't remember</b>      3       <b>that. But he's wrong.</b>      4        MR. BRANTINGHAM: Just -- yeah. So      5 wait for the question and respond --      6       Q. You got to listen to --      7        MR. BRANTINGHAM: -- specifically to      8 it.      9       <b>A. All right.</b>      10      Q. Nope. You hang onto that, because I'm      11 going to ask you some questions from it.      12      <b>A. Uh-huh.</b></p> <p>13      14      15      16      17      18      19      20      21      22      23      24      25</p> 	<p style="text-align: center;">Page 28</p> <p>1       <b>A. Uh-huh.</b>      2       Q. -- when it got to the operating room,      3 it would have been too late; right?      4        MR. BRANTINGHAM: Object to the form,      5 foundation. You can answer.      6       <b>A. What do you mean by "too late?"</b>      7       Q. By the time that donor heart got to the      8 operating room, you had already taken Noah      9 Leopold's heart out; right?      10      <b>A. Yeah. Because we rely on the -- on the</b>      11 <b>team that we sent to look at the heart. So --</b>      12 <b>so normally the -- the team looks at it at the</b>      13 <b>donor site, then when they are about to take off</b>      14 <b>and then when they land, so I talked to my team</b>      15 <b>in that way. And then it is the best, the</b>      16 <b>clinical practice, to start the case when the</b>      17 <b>heart is meant to look good, and then as soon as</b>      18 <b>they arrive, be ready to sew it in. So we</b>      19 <b>minimize the time on the OCS to minimize the</b>      20 <b>time of the heart out of the body.</b>      21      Q. How long can the heart stay viable on      22 OCS?      23      <b>A. We don't know for sure.</b>      24      Q. Do you remember giving a presentation      25 where you talked that "Most people who have" --</p>
<p style="text-align: center;">Page 27</p> <p>1       </p> <p>2      3      4      5</p> <p>6       Q. Do you remember anybody saying anything      7 to you about the heart not being robust --      8       <b>A. I don't remem --</b>      9       Q. -- while it was on OCS?      10      <b>A. I don't remember that.</b>      11      Q. If somebody had told you that the heart      12 did not look robust while it was on OCS, would      13 that have been noteworthy to you?      14      <b>A. Of course I would review that.</b>      15      Q. What do you mean you would review that?      16      <b>A. Yeah. If somebody tells me that the --</b>      17 <b>that the heart is bad, that could be wrong or</b>      18 <b>right, so I have to review it, look at it</b>      19 <b>myself.</b>      20      Q. You couldn't look at the heart until it      21 came to the operating room; right?      22      <b>A. Yeah. Could I look? No. I --</b>      23       <b>That is physically impossible.</b>      24      Q. If the heart had been not robust, or      25 "bad" to use your words, --</p>	<p style="text-align: center;">Page 29</p> <p>1       there's actually a slash here -- "Most people      2 who've been involved with the OCS think that      3 total body time can be eight hours or even      4 more?"      5       <b>A. It's possible, but the longer you are</b>      6 <b>on the OCS, the more edema you could have on the</b>      7 <b>myocardium. So the shorter time on the OCS, the</b>      8 <b>better.</b>      9       Q. How long does it take for a heart to      10 get from the airport in Rochester to the      11 operating room?      12      <b>A. Fifteen minutes.</b>      13      Q. So if you had wanted to, you could have      14 waited 15 minutes to get your eyes on this heart      15 before you took out Noah's heart.      16      <b>A. I have trust in my team. They are</b>      17 <b>competent professionals.</b>      18      Q. Wasn't my question.      19       My question is if you --      20      <b>A. I answer it.</b>      21      Q. With respect, you didn't. My question      22 wasn't do you have confidence in your team.      23      <b>A. Yeah. But --</b>      24      MR. BRANTINGHAM: Let him ask the      25 question, doctor, and then you can answer.</p>

<p style="text-align: right;">Page 30</p> <p>1 Q. My question was: Could you have waited 2 if you wanted to?</p> <p>3 <b>A. Yeah. But that will be a bad clinical</b> 4 <b>decision because you have to shorten up the time</b> 5 <b>on the OCS.</b></p> <p>6 Q. Do you remember doing a presentation 7 with Dr. Paul Friedman from Mayo in July of 8 2023?</p> <p>9 <b>A. Yes.</b></p> <p>10 Q. Do you remember that presentation?</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. What was it about?</p> <p>13 <b>A. About the techniques for heart</b> 14 <b>transplantation, one, you know, the ex vivo</b> 15 <b>heart perfusion.</b></p> <p>16 Q. Yeah. Do you remember during that 17 presentation saying to Dr. Friedman, "So what 18 happens is, for a reason that we completely do 19 not understand, the heart gets edematous, so you 20 have to examine the heart before implanted to 21 make sure you know that it hasn't gotten that 22 edematous." Does that sound like something you 23 would have said?</p> <p>24 <b>A. I don't remember exactly, but that</b> 25 <b>doesn't mean to be by me, it means to be done by</b></p>	<p style="text-align: right;">Page 32</p> <p>1 written by your colleagues at Mayo Jacksonville, 2 they describe the process for transplanting an 3 OCS heart. And they say, "Once the heart 4 reaches the recipient OR on the OCS machine, its 5 contractility is reassessed. Based on heart 6 function, other hemodynamic parameters, and 7 lactate levels, if it is decided to proceed with 8 the transplant, the first step is closure of the 9 aortic vent," and yadda yadda yadda. Do you 10 know whether your colleagues at Mayo 11 Jacksonville wait until the heart arrives and 12 can be reassessed in the operating room before 13 they irreversibly remove the patient's native 14 heart?</p> <p>15 MR. BRANTINGHAM: Foundation.</p> <p>16 <b>A. I --</b></p> <p>17 MR. BRANTINGHAM: You can answer.</p> <p>18 <b>A. I don't know if they wait.</b></p> <p>19 Q. But you told -- but you told me before 20 that it would be bad clinical practice to do 21 that. Do you think your colleagues at Mayo 22 Jacksonville are committing malpractice?</p> <p>23 <b>A. No. I don't --</b></p> <p>24 MR. BRANTINGHAM: Foundation.</p> <p>25 <b>A. -- I don't think it's --</b></p>
<p style="text-align: right;">Page 31</p> <p>1 <b>the surgical team. You know, it's impossible to</b> 2 <b>work on -- on your own. You need to rely on</b> 3 <b>your surgical team, and that was done.</b></p> <p>4 Q. Who is Dr. Mohammad Alomari?</p> <p>5 <b>A. Mohammad? Who's that one?</b></p> <p>6 Q. Do you recognize that name?</p> <p>7 <b>A. Mohammad?</b></p> <p>8 Q. Yeah. One of your colleagues in 9 Jacksonville, at Mayo Jacksonville?</p> <p>10 <b>A. I -- I don't think I know him.</b></p> <p>11 Q. Dr. Pankaj Garg, does that name ring a bell?</p> <p>12 <b>A. No.</b></p> <p>13 Q. Okay. John Yazji?</p> <p>14 <b>A. No.</b></p> <p>15 Q. Dr. Wadiwala?</p> <p>16 <b>A. No.</b></p> <p>17 Q. Well I'll tell you that all of those guys were involved in writing an article entitled "Is the Organ Care System Still the First Choice With Emerging New Strategies for DCD in Heart Transplant." Does that article ring any bells for you?</p> <p>18 <b>A. I -- I haven't heard about that study.</b></p> <p>19 Q. I will tell you that in this article,</p>	<p style="text-align: right;">Page 33</p> <p>1 MR. BRANTINGHAM: Hang on just one sec, 2 doctor. Let me -- I have to get an objection 3 out. Foundation. You can go ahead and answer.</p> <p>4 <b>A. Well I -- I think, as I said, that the</b> 5 <b>longer the time on the OCS, you know, the worse</b> 6 <b>the results. Whether how many minutes matter or</b> 7 <b>not, you know, might be a matter of debate, it</b> 8 <b>has not been determined, so I would not accuse</b> 9 <b>them of malpractice. It is -- is they might</b> 10 <b>have a different approach, but it's not proven</b> 11 <b>that it's better or worse.</b></p> <p>12 Q. Well didn't you tell me, when I asked 13 you if you could have waited that 15 minutes, 14 "Yes, I could have, but it would be bad clinical 15 practice?"</p> <p>16 <b>A. Yeah, yeah. From my standpoint, I</b> 17 <b>said, you know -- again, I'm going to repeat to</b> 18 <b>you, maybe you're not listening -- the longer --</b> 19 <b>that the longer that you are on the OCS, the</b> 20 <b>more edema you get. So it is, for me,</b> 21 <b>preferable to, you know, be ready to sew the</b> 22 <b>heart in once it arrives. And provided that you</b> 23 <b>have trust on your surgical team, which I do.</b></p> <p>24 Q. Let's go back to my question, though, 25 because that wasn't my question.</p>

<p style="text-align: center;">Page 34</p> <p>1        My question was: Didn't you tell me 2        under oath a few minutes ago, when I asked 3        you --</p> <p>4        <b>A. Uh-huh.</b></p> <p>5        Q. -- if you could have waited, you said, 6        "Yes, I could, but that would be bad clinical 7        practice?"</p> <p>8        MR. BRANTINGHAM: Let me just object -- 9        object that I think that is quite explicitly 10      reasking the exact same question you think you 11      already asked, so asked and answered.</p> <p>12      MR. THOMPSON: He didn't answer it.</p> <p>13      Q. But go ahead.</p> <p>14      MR. BRANTINGHAM: Go ahead.</p> <p>15      <b>A. Well I -- I think I would -- I would 16      not do that because that would result in -- in a 17      worse clinical result.</b></p> <p>18      Q. Okay. Did you tell me that waiting 19      would be bad clinical practice?</p> <p>20      MR. BRANTINGHAM: I mean we can read 21      back the transcript, but it's -- it's been asked 22      and answered. Maybe one more time, go ahead and 23      answer.</p> <p>24      <b>A. I would prefer not to wait to decrease 25      the -- the edema on the heart.</b></p>	<p style="text-align: center;">Page 36</p> <p>1        colleague of anything.</p> <p>2        <b>A. Well that's what you're implying, so I 3        am answering your question.</b></p> <p>4        Q. Don't try to read into my implication. 5        Just answer the question I'm asking.</p> <p>6        <b>A. I -- I answer it.</b></p> <p>7        Q. No, you didn't.</p> <p>8        MR. BRANTINGHAM: Hold on one sec, 9        doctor. Should we read back the original answer 10      so that we have clarity on --</p> <p>11      MR. THOMPSON: No, because now he's 12      going to --</p> <p>13      MR. BRANTINGHAM: -- what was said?</p> <p>14      MR. THOMPSON: -- because now he put -- 15      I'm good. Do you have an objection?</p> <p>16      MR. BRANTINGHAM: My objection I think 17      is asked and answered.</p> <p>18      MR. THOMPSON: Great. Thank you.</p> <p>19      MR. BRANTINGHAM: Okay.</p> <p>20      Q. Is it bad clinical practice to wait or 21      isn't it?</p> <p>22      MR. BRANTINGHAM: You can answer that 23      question.</p> <p>24      <b>A. I -- I think it would produce more 25      edema on the heart, so I would not do that.</b></p>
<p style="text-align: center;">Page 35</p> <p>1        Q. Wasn't my question. I didn't ask you 2        if you preferred to wait. I asked you if you 3        remember telling me under oath that waiting 4        would be bad clinical practice.</p> <p>5        <b>A. Well you are -- you are trying to bring 6        up a controversy with my colleagues in Mayo 7        Florida. I don't think that's appropriate. 8        Maybe my words were not exactly right, but I 9        think it's preferable to not let the heart get 10      more edematous and to decrease the time on the 11      OCS.</b></p> <p>12      Q. Okay. So now you'd like to retract 13      what you said earlier that it was bad clinical 14      practice?</p> <p>15      <b>A. Well in -- in the terms that -- your 16      legal terms maybe; in my -- in my clinical 17      positive way probably is appropriate. But you 18      understand one thing, I understand a different 19      one because we have different backgrounds.</b></p> <p>20      Q. I'm asking you for your own words, 21      doctor. Do you think it would be bad clinical 22      practice to wait or don't you?</p> <p>23      <b>A. I would not accuse a colleague of bad 24      clinical practice.</b></p> <p>25      Q. I wasn't asking you if you accused a</p>	<p style="text-align: center;">Page 37</p> <p>1        Q. That wasn't my question.</p> <p>2        <b>A. I answer your question.</b></p> <p>3        Q. No, you didn't. You answered a 4        different question that I didn't ask, and we're 5        going to keep asking this question until you 6        actually answer it.</p> <p>7        <b>A. Then I think it's not a -- 8        Then I don't think so.</b></p> <p>9        Q. You don't think it's bad clinical 10      practice.</p> <p>11      <b>A. In legal terms, no.</b></p> <p>12      Q. Okay. You just think it's not 13      something you would do.</p> <p>14      <b>A. Yeah. I would not do clinically 15      because I want the best result for my patient.</b></p> <p>16      Q. And you think that doing that, waiting, 17      can lead to worse clinical outcomes.</p> <p>18      <b>A. Yes.</b></p> <p>19      Q. Are you going to call up your 20      colleagues in Jacksonville and tell them, "Hey 21      guys, what you're doing may lead to bad clinical 22      outcomes, and since we care about saving 23      patients' lives here at the Mayo Clinic, maybe 24      you should think about doing it differently?"</p> <p>25      MR. BRANTINGHAM: Object to the form of</p>

<p style="text-align: right;">Page 38</p> <p>1       the question and the foundation. You can 2       answer.</p> <p>3       <b>A. This --</b></p> <p>4       <b>To say that, you know, I will have</b> 5       <b>to -- I need to have a -- a study about the</b> 6       <b>times on the OCS, and we don't have that so far</b> 7       <b>in the literature.</b></p> <p>8       Q. None of that was my question. 9       You told me that in your opinion, as 10      the director of the heart/lung transplant 11      program at Mayo Clinic Rochester, waiting until 12      the heart arrives in the operating room before 13      you explant the native heart leads to worse 14      clinical outcomes. My question is: Are you 15      going to contact your colleagues at Mayo 16      Jacksonville and tell them, "Hey guys, what 17      you're doing may lead to worse clinical 18      outcomes?"</p> <p>19      MR. BRANTINGHAM: Object to the form. 20      You can answer.</p> <p>21      <b>A. I will not do that until there is a</b> 22      <b>study that would, you know, resolve that</b> 23      <b>question.</b></p> <p>24      Q. Do you remember what this heart looked 25      like when it came out of the box?</p>	<p style="text-align: right;">Page 40</p> <p>1       <b>fine.</b></p> <p>2       Q. How big of a size mismatch was there?</p> <p>3       <b>A. Thirty-percent different.</b></p> <p>4       Q. And in your clinical view that is 5       significant; right?</p> <p>6       <b>A. Well it's --</b></p> <p>7       <b>I have transplanted many hearts that</b> 8       <b>have been larger than 30 percent successfully.</b></p> <p>9       Q. My question was: Is a 30-percent size 10      mismatch, in your clinical view, significant?</p> <p>11      <b>A. Yeah, it's significant.</b></p> <p>12      Q. Did you think going into this surgery 13      there was going to be a 30-percent size 14      mismatch?</p> <p>15      <b>A. Yeah, because the -- the donor was</b> 16      <b>larger, and that's good for the hemodynamics of</b> 17      <b>the recipients. So the larger the size is, the</b> 18      <b>hemodynamics are better after a heart</b> 19      <b>transplantation.</b></p> <p>20      Q. Do you remember talking with members of 21      the Leopold family after this catastrophic 22      failed transplant?</p> <p>23      <b>A. I -- I remember --</b></p> <p>24      MR. BRANTINGHAM: Object to the form of 25      the question. Go ahead, you can answer, doctor.</p>
<p style="text-align: right;">Page 39</p> <p>1       <b>A. Yes.</b></p> <p>2       Q. What did it look like?</p> <p>3       <b>A. Excellent function.</b></p> <p>4       Q. What color was it?</p> <p>5       <b>A. Like the color of a heart, like yellow</b> 6       <b>and red.</b></p> <p>7       Q. Any oth --</p> <p>8       Anything else you can describe for me?</p> <p>9       <b>A. There was some ecchymosis, you know, on</b> 10      <b>the heart, that's meaning a little bit of</b> 11      <b>bruising.</b></p> <p>12      Q. Anything else you can describe for me?</p> <p>13      <b>A. The squeezing function was excellent.</b></p> <p>14      Q. Did you notice, when the heart came out 15      of the box, that it was larger than expected?</p> <p>16      <b>A. No, it was not larger than expected.</b></p> <p>17      Q. When you tried to transplant it into 18      Noah there was a significant size mismatch; was 19      there not?</p> <p>20      <b>A. Yeah, that's -- there was a size</b> 21      <b>mismatch. That doesn't -- it's not the same</b> 22      <b>that -- larger than expected. It was a size</b> 23      <b>mismatch, so because I'm a transplant surgeon, I</b> 24      <b>made the surgical maneuvers to fix that, and</b> 25      <b>those maneuvers were successful, and so it was</b></p>	<p style="text-align: right;">Page 41</p> <p>1       <b>A. I -- I remember talking to them.</b></p> <p>2       Q. Do you remember telling them that you 3       knew right away that the heart was bruised and 4       didn't look great, but by then it was too late?</p> <p>5       <b>A. Well it was -- was -- you know, had</b> 6       <b>bleeding several hours after it was implanted.</b> 7       <b>It was bruised at the beginning, but just as</b> 8       <b>described in the operative note, it is mildly</b> 9       <b>bruised as is in the usual OCS cases.</b></p> <p>10      Q. Mr. Leopold's family is going to 11      testify that you told them that you knew right 12      away when that heart came out of the box that it 13      was bruised and it didn't look great, but by 14      then it was too late because Noah's native heart 15      had already been explanted. If -- you got to 16      let me ask my question -- if they testify that 17      you told them that, are you going to deny it?</p> <p>18      <b>A. I -- I --</b></p> <p>19      In terms of the timing, I'm going to 20      deny it. Because what had happened is it was, 21      you know, severely bruised. If you -- you know, 22      this is a qual -- qualitative description, you 23      know, more like a hematoma, so big-time 24      bruising. That -- that's what I told them that, 25      you know, happened several hours later as, you</p>

<p style="text-align: right;">Page 42</p> <p>1 know, the transplant went through. But -- but 2 the bruising was mild.</p> <p>3 Q. And you're sticking right now with you 4 thought the heart itself looked excellent when 5 it first came out of the box.</p> <p>6 A. Yes.</p> <p>7 Q. When you accepted this heart for 8 transplant, did you know about the donor's 9 social and health history?</p> <p>10 A. Yes.</p> <p>11 Q. Did you know that the donor was a meth 12 addict?</p> <p>13 A. Yes, sir.</p> <p>14 Q. Did you know that the donor had died of 15 a meth overdose?</p> <p>16 A. Yes.</p> <p>17 Q. Did you know that the donor had died of 18 an intracranial hemorrhage that was brought on 19 by that meth overdose?</p> <p>20 A. Yes.</p> <p>21 Q. You know that heart transplant 22 recipients of donors with intracranial 23 hemorrhage have worse survival; right?</p> <p>24 A. That has not been established clearly 25 in the literature.</p>	<p style="text-align: right;">Page 44</p> <p>1 matched in risk factors, so the difference could 2 have been different risk factors. For example, 3 the group with intracranial hemorrhage were 4 older, so that could have been the reason of the 5 one-percent difference.</p> <p>6 Q. None of that was my question.</p> <p>7 When you published that abstract with 8 the title "Heart Transplant Recipients of Donors 9 with Intracranial Hemorrhage Have Worse 10 Survival," did you intend to say "Heart 11 Transplant Recipients of Donors with 12 Intracranial Hemorrhage Have Worse Survival, But 13 It's Not Clinically Significant?"</p> <p>14 MR. BRANTINGHAM: I just object to the 15 form of the question. Go ahead.</p> <p>16 A. The --</p> <p>17 I was not the first nor the last 18 author. So I -- I --</p> <p>19 In terms that this was submitted to a 20 meeting, I thought it was reasonable, but it's 21 not something that could be accepted in regular 22 clinical practice because that will leave many, 23 many patients with no life-saving heart 24 transplant.</p> <p>25 Q. None of that was my question either.</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. You wrote an article that literally has 2 that as the title; right?</p> <p>3 A. Yeah. But the title is one thing, and 4 the other thing is how it -- how it looks like.</p> <p>5 Q. How what looks like?</p> <p>6 A. Because if you read --</p> <p>7 I'm going to explain the -- the 8 abstract. The abstract shows that in the United 9 States over 6,000 patients have been 10 transplanted with intracranial hemorrhage, so 11 kind of two years' worth of heart transplant 12 practice in the whole United States. So that 13 obviously -- it should tell you that taking 14 donors with intracranial hemorrhage is a 15 standard practice. And if you -- 6,000 heart 16 transplants. And then if you see the abstract 17 with an academic eye, you will see the 18 difference that was encountered was a 19 one-percent difference, between, you know, 20 11.9 -- so 12 percent and 13-point-something 21 percent, one percent difference. Not clinically 22 significant, just the study signify significant. 23 And one more issue with that is that when 24 there's a comparison of intracranial hemorrhage 25 versus other type of strokes, the groups are not</p>	<p style="text-align: right;">Page 45</p> <p>1 Let me try again. I'll try a different 2 question.</p> <p>3 With respect to the clinical 4 significance of these findings, do you remember 5 what the conclusion is in this abstract?</p> <p>6 A. That -- that you need to be cautious 7 with intracranial-hemorrhage donors.</p> <p>8 Q. And matched carefully with the 9 appropriate recipient; right?</p> <p>10 A. And --</p> <p>11 Yeah.</p> <p>12 Q. Got it.</p> <p>13 Were you involved in any 14 informed-consent discussions with Mr. Leopold 15 before this surgery?</p> <p>16 A. Yes.</p> <p>17 Q. When did you meet with him?</p> <p>18 A. The day before the transplant.</p> <p>19 Q. The day before the transplant?</p> <p>20 A. Well I mean during the day. You know, 21 the transplant was during the night, so that's 22 what I mean, the day.</p> <p>23 Q. Got it.</p> <p>24 A. Actually I think it was -- you know, 25 the transplant was in the night, so in -- in</p>

12 (Pages 42 to 45)

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<p style="text-align: right;">Page 46</p> <p>1     <b>that. There's two days in "during the night,"</b>  2     <b>so in the -- that day of that night, the</b>  3     <b>previous day of that night I talked to him and</b>  4     <b>the family.</b></p> <p>5     Q. Do you remember about what time that  6     was?</p> <p>7     <b>A. Maybe 3:00 p.m. Maybe. I can't</b>  8     <b>remember.</b></p> <p>9     Q. Do you remember -- do you remember  10    anything about the conversation?</p> <p>11    <b>A. I remember there was a kind of half-an-</b>  12    <b>hour conversation and that they -- all their</b>  13    <b>questions were answered.</b></p> <p>14    Q. Did Noah have lots of questions?</p> <p>15    <b>A. Yes.</b></p> <p>16    Q. Like what?</p> <p>17    <b>A. I don't remember.</b></p> <p>18    Q. You don't remember a single one?</p> <p>19    <b>A. Like "How is the donor?" "It's a good</b>  20    <b>donor."</b></p> <p>21    Q. He asked "How's the donor?" and you  22    said "It's a good donor?"</p> <p>23    <b>A. "It's a good donor."</b></p> <p>24    Q. When he asked "How's the donor?" and  25    you said, "Oh, it's a good donor," --</p>	<p style="text-align: right;">Page 48</p> <p>1     the benefits and the risks of the organ that  2     you're planning on implanting in his body?</p> <p>3     <b>A. We talked before the patient is listed,</b>  4     <b>so we got a -- a surgical consult either by me</b>  5     <b>or one of my heart transplant colleagues. And</b>  6     <b>as -- and as I said, you know, I talked to the</b>  7     <b>recipient, you know, before the transplant, as I</b>  8     <b>said I did.</b></p> <p>9     Q. Okay. None of that's my question.</p> <p>10    My question is: When you had the  11    conversation with Noah, did you talk with him  12    about the benefits and risks, not of the overall  13    procedure, but of the specific organ you were  14    planning on implanting in his body?</p> <p>15    <b>A. Well they have already been consulted</b>  16    <b>by the whole team about that for extensive and</b>  17    <b>overwhelming period of time. So we normally</b>  18    <b>would tell -- you know, ask if there are any</b>  19    <b>further questions of what has been already</b>  20    <b>discussed, because the patient had had many</b>  21    <b>discussions with the cardiologist, with another</b>  22    <b>heart surgeon and so on and so forth, so we, you</b>  23    <b>know, don't want to be redundant, and then, you</b>  24    <b>know, ask if there's anything new.</b></p> <p>25    Q. Okay.</p>
<p style="text-align: right;">Page 47</p> <p>1     <b>A. Yeah.</b></p> <p>2     Q. -- did he ask you any follow-up  3     questions on that?</p> <p>4     <b>A. I don't remember.</b></p> <p>5     Q. When he asked you "How is the donor?"  6     and you said "Good donor," did you tell him "But  7     we've got to consider this donor with caution  8     because he had an intracranial hemorrhage?"</p> <p>9     <b>A. It is -- it is forbidden by UNOS</b>  10    <b>policies to give healthcare information or</b>  11    <b>mechanism of death --</b></p> <p>12    Q. Right.</p> <p>13    <b>A. -- to the donor, so we would not</b>  14    <b>discuss that.</b></p> <p>15    Q. Okay. So what is your understanding of  16    what your obligation is when you're providing  17    informed consent?</p> <p>18    <b>A. It is to tell the patient about the</b>  19    <b>procedure they are going to have.</b></p> <p>20    Q. Is that it?</p> <p>21    <b>A. Yeah. The benefits and the risks.</b></p> <p>22    Q. Benefits and the risks of what?</p> <p>23    <b>A. Of the procedure, meaning heart</b>  24    <b>transplantation.</b></p> <p>25    Q. Do you talk with them in the -- about</p>	<p style="text-align: right;">Page 49</p> <p>1     <b>A. In general terms. You know, I can't</b>  2     <b>remember what I talked to him and the family, I</b>  3     <b>just remember that it was a half an hour.</b></p> <p>4     Q. This --</p> <p>5     Discussions that he had had in the days  6     and weeks prior to the discussion you had with  7     him, nobody knew anything about the donor heart  8     that was going to be implanted in him then;  9     right?</p> <p>10    <b>A. Do you think we have a crystal ball or</b>  11    <b>something about how the donor's going to be?</b></p> <p>12    Q. Well that's exactly my point. You  13    don't have a crystal ball, so you --</p> <p>14    <b>A. Yeah.</b></p> <p>15    Q. -- nobody at Mayo would have been able  16    to tell Noah anything about the risks and  17    benefits of that specific organ until the  18    morning of August 29th; right?</p> <p>19    <b>A. No. We could not tell the specific, as</b>  20    <b>I -- as we said, because, you know, UNOS forbids</b>  21    <b>that.</b></p> <p>22    Q. UNOS doesn't forbid that and neither  23    does the OPTN.</p> <p>24    <b>A. It's the same thing.</b></p> <p>25    Q. Yeah.</p>

<p style="text-align: right;">Page 50</p> <p>1           MR. BRANTINGHAM: Just hold on --      2       wait --      3       <b>A. No, no. It does. It does.</b>      4       Q. Is it --      5       <b>A. It does forbid that.</b>      6       MR. BRANTINGHAM: Hold on. Hold on.      7       Hold on. Wait for a question.      8       Q. I'm going to ask a question.      9       MR. BRANTINGHAM: Wait for a question.      10      Q. The question --      11      So what is your basis for saying that      12     you are forbidden from telling somebody that the      13     donor died of an intracranial hemorrhage?      14      <b>A. Because there's UNOS, you know, bylaws</b>      15     <b>and then you cannot do that.</b>      16      Q. Are you talking about the OPTN Guidance      17     on --      18      <b>A. On UNOS.</b>      19      Q. Huh?      20      <b>A. On UNOS.</b>      21      Q. UNOS or OPTN?      22      <b>A. Well it's the same thing.</b>      23      Q. They're two different organizations;      24     aren't they?      25      <b>A. Well they overlap.</b></p>	<p style="text-align: right;">Page 52</p> <p>1       <b>overlap.</b>      2       Q. Have you ever seen OPTN's Guidance for      3     Donor and Recipient Information Sharing?      4       <b>A. Yeah, I think I saw that.</b>      5       Q. The guidance that --      6       Do you know what OPTN is?      7       <b>A. Organ Procurement Transplantation</b>      8     <b>Network.</b>      9       Q. How do they relate to your practice?      10      <b>A. So they establish kind of the framework</b>      11     <b>of the practice, transplant practice.</b>      12      Q. What OPTN says is that "Deceased donor      13     information routinely shared with the      14     recipients/recipient families should be limited      15     to information required as part of the recipient      16     informed consent process for transplantation."      17     What part of that says you can't tell them that      18     they died of an intracranial hemorrhage?      19      MR. BRANTINGHAM: I just object to form      20     and note for the record the pat -- the witness      21     is not being shown the document that is being      22     read to him.      23      Q. I just read you the statement. What      24     part of that --      25      <b>A. No -- no --</b></p>
<p style="text-align: right;">Page 51</p> <p>1       Q. How so?      2       <b>A. Because they take care of a heart</b>      3     <b>tran -- I mean transplantation in the U.S.</b>      4       Q. Well sure, so does LifeSource. Is      5     LifeSource and the OPTN the same thing?      6       <b>A. Yeah. So, no, they overlap.</b>      7       Q. Wasn't my question. You keep telling      8     me that UNOS and OPTN are the same thing.      9       <b>A. Well --</b>      10      MR. BRANTINGHAM: Hold -- just wait --      11     wait -- wait for him to get to an actual --      12      Q. You got to wait for the question.      13      MR. BRANTINGHAM: There's a lot of      14     words before an actual question. Let all the      15     words come, --      16      THE WITNESS: Okay.      17      MR. BRANTINGHAM: -- and then when      18     there's a real question, answer that question.      19      THE WITNESS: Okay.      20      BY MR. THOMPSON:      21      Q. Is it really your testimony that OPTN      22     and UNOS are the same thing?      23      MR. BRANTINGHAM: Object to form. Go      24     ahead, doctor, you can answer.      25      <b>A. Honestly, I'm not sure. They usually</b></p>	<p style="text-align: right;">Page 53</p> <p>1       Q. -- says you can't tell them there's an      2     intracranial hemorrhage?      3       <b>A. I don't know the exact document that</b>      4     <b>you have, but I've read that they can't be</b>      5     <b>informed about the cause of death.</b>      6       Q. You read that somewhere.      7       <b>A. Yes.</b>      8       Q. That you're prohibited from doing that.      9       <b>A. Yes, sir.</b>      10      Q. Do you have an understanding that what      11     Minnesota law requires, when you're providing      12     informed consent to a patient, is you have to      13     give the patient all of the information that a      14     reasonable patient in that person's position      15     would find significant in making a decision      16     about their own healthcare?      17      <b>A. I don't know about that. I'm not a</b>      18     <b>lawyer.</b>      19      Q. Do you strive, when you are providing      20     informed consent to patients, to give a patient      21     all the information they would find significant?      22      <b>A. Yes, we do that in the -- in the</b>      23     <b>consult, official consult, surgical now before</b>      24     <b>the patient is listed, --</b>      25      Q. I'm --</p>

<p style="text-align: right;">Page 54</p> <p>1       <b>A. -- as Dr. Daly did.</b></p> <p>2       Q. Yep. I'm sticking with your</p> <p>3       conversation. When you provided informed</p> <p>4       consent to Noah --</p> <p>5       When Dr. Daly talked to Noah, Dr. Daly</p> <p>6       didn't know that this donor organ was going to</p> <p>7       be coming from a meth addict who died of an</p> <p>8       intracranial hemorrhage; right?</p> <p>9       <b>A. Yep. We -- we should not tell the</b></p> <p>10      <b>patient that.</b></p> <p>11      Q. Wasn't my question.</p> <p>12      My question was: When Dr. Daly talked</p> <p>13      to Mr. Leopold, Dr. Daly didn't know that the</p> <p>14      heart was coming from a meth addict who died of</p> <p>15      an intracranial hemorrhage; did he?</p> <p>16      <b>A. Well he didn't know, --</b></p> <p>17      Q. Did he --</p> <p>18      <b>A. -- but he knew that 20 or 30 percent of</b></p> <p>19      <b>the donors are -- in the U.S. are from drug</b></p> <p>20      <b>overdose, so we discuss that.</b></p> <p>21      Q. "We" being who?</p> <p>22      <b>A. We, any transplant professional, you</b></p> <p>23      <b>know, would know that 20 or 30 percent are</b></p> <p>24      <b>from -- from a drug addict in the U.S. from drug</b></p> <p>25      <b>overdose.</b></p>	<p style="text-align: right;">Page 56</p> <p>1       MR. BRANTINGHAM: Let him -- wait for</p> <p>2       the next question.</p> <p>3       Q. Hang on. I know that you're a busy</p> <p>4       man. I know that you don't want to be here. I</p> <p>5       get that. I would like to go home to</p> <p>6       Minneapolis as well. This will go a lot more</p> <p>7       smoothly if you answer the questions that I'm</p> <p>8       asking. Just answer that question, then stop,</p> <p>9       let me ask another question rather than</p> <p>10      answering my question and then trying to read</p> <p>11      into where I'm trying to go with it and give me</p> <p>12      a bunch of other information that has nothing to</p> <p>13      do with the question that I asked. So --</p> <p>14      <b>A. I think the situation is different. I</b></p> <p>15      <b>think the situation is that you don't like my</b></p> <p>16      <b>answers, and I -- you have to accept my answers.</b></p> <p>17      <b>You know, I'm a medical professional.</b></p> <p>18      Q. Okay. Fair -- I --</p> <p>19      It's on the record now that I'm trying</p> <p>20      really hard to get through this, and if we got</p> <p>21      to be here all night, we'll be here all night.</p> <p>22      I've got seven and a half hours with you, so --</p> <p>23      Let's go back to my question. When Dr.</p> <p>24      Daly talked to Noah, he didn't know that the</p> <p>25      heart that was going to be implanted into Noah's</p>
<p style="text-align: right;">Page 55</p> <p>1       Q. Which means that 70 or 80 percent of</p> <p>2       them do not come from a drug overdose; right?</p> <p>3       <b>A. Yes.</b></p> <p>4       Q. Which means that, assuming that Dr.</p> <p>5       Daly had that discussion with Noah, Noah would</p> <p>6       have understood that there was a seven- or</p> <p>7       eight-out-of-ten chance that the donor for his</p> <p>8       heart would not have had a drug overdose; right?</p> <p>9       <b>A. Yeah, that is possible; however, the --</b></p> <p>10      <b>he was told about this was an increased-risk</b></p> <p>11      <b>donor. And increased-risk donor, Mr. Leopold</b></p> <p>12      <b>knew very clearly that it could be, you know, a</b></p> <p>13      <b>drug addict, and -- and he consented for that</b></p> <p>14      <b>and that's documented.</b></p> <p>15      Q. Okay. So first of all, please listen</p> <p>16      to my question and just answer my question. My</p> <p>17      question didn't have anything to do with any of</p> <p>18      that.</p> <p>19      <b>A. Well I'm not going to answer what you</b></p> <p>20      <b>want.</b></p> <p>21      Q. Well you've got to answer my questions</p> <p>22      though.</p> <p>23      <b>A. Yeah. I did.</b></p> <p>24      MR. BRANTINGHAM: Hold on, doctor.</p> <p>25      Q. Just hang on. Hang on. Hang on.</p>	<p style="text-align: right;">Page 57</p> <p>1       chest was coming from a meth addict who had an</p> <p>2       intracranial hemorrhage; isn't that true?</p> <p>3       <b>A. No, he didn't --</b></p> <p>4       <b>Yeah. He didn't know.</b></p> <p>5       Q. The only surgeon who provided informed</p> <p>6       consent to Noah after that information became</p> <p>7       available was you; isn't that true?</p> <p>8       <b>A. The con --</b></p> <p>9       <b>The informed consent is -- is done</b></p> <p>10      <b>previously --</b></p> <p>11      Q. Uh-huh.</p> <p>12      <b>A. -- in the surgical note. It's a --</b></p> <p>13      <b>it's a team approach.</b></p> <p>14      Q. Wasn't my question. We'll go back to</p> <p>15      my question.</p> <p>16      The only surgeon who provided informed</p> <p>17      consent to Noah after the information about the</p> <p>18      donor became available was you; isn't that true?</p> <p>19      <b>A. The surgeon --</b></p> <p>20      <b>Yeah. Uh-huh.</b></p> <p>21      Q. So let's stick specifically with what</p> <p>22      you told Noah. You told him it was a good</p> <p>23      donor, --</p> <p>24      <b>A. Uh-huh.</b></p> <p>25      Q. -- and then you talked with him about</p>

<p style="text-align: center;">Page 58</p> <p>1 the risks and benefits just of the transplant    2 procedure, but not the risks and benefits of the    3 donor organ. Do I have that right?</p> <p>4     <b>A. No.</b></p> <p>5     Q. What part do I have wrong?</p> <p>6     <b>A. Because how the transplant procedure    7 could be separated from the donor procedure.</b></p> <p>8     Q. Okay. Then tell me with as much    9 specificity as you can what you told Noah about    10 the potential risks of this specific donor    11 organ.</p> <p>12     <b>A. I -- I thought it -- and -- it was    13 an --</b></p> <p>14         <b>That it was an excellent donor and that    15 normally -- I can't recall exactly what -- what    16 was the conversation, as I said before -- but,    17 you know, the -- the risk of cardiac surgery,    18 you know, was done. Risks of cardiac surgery    19 are stroke, bleeding, wound infection, renal    20 failure, the whole medicine is a risk. That's    21 the risk.</b></p> <p>22     Q. None of that answered my question at    23 all. I asked you what specifically did you tell    24 Noah about the risks of this specific donor    25 organ.</p>	<p style="text-align: center;">Page 60</p> <p>1 with him about. We're sticking with you. So --</p> <p>2     <b>A. Yeah. That's what --</b></p> <p>3     Q. Hold on. Hold on.</p> <p>4     <b>A. But let -- but let me -- you -- you    5 are --</b></p> <p>6     MR. BRANTINGHAM: Wait for --</p> <p>7     <b>A. You allude to me, so I need to answer.    8 Because we are part of the team that    9 informs things to the -- to the -- to the    10 recipient, so I rely in my colleagues, my    11 cardiology, my transplant coordinator to give    12 the most information that we can to the patient.    13 And I went there and spent a half an hour at    14 least talking to them and doing the best job    15 that we can.</b></p> <p>16     Q. Great. Now I've talked to Dr.    17 Rosenbaum and I'll probably talk to the    18 transplant coordinator. What I'm interested in    19 right now, though, is talking to you about what    20 you told Mr. Leopold, so I'm going to go back to    21 my question.</p> <p>22     When you spent that half hour talking    23 to Noah Leopold, did you tell him anything about    24 the risks of this donor organ other than just    25 saying "This is an excellent donor?"</p>
<p style="text-align: center;">Page 59</p> <p>1     <b>A. Again -- again, I already told you that    2 we don't talk in specifics because that's    3 banned, --</b></p> <p>4     Q. So --</p> <p>5     <b>A. -- is -- is confidential information    6 about the donor.</b></p> <p>7     Q. So what you told him was this was an    8 excellent donor and that's it.</p> <p>9     <b>A. Yeah. And if they had any question --    10 and I don't recall what other question they    11 have, but I remember that I stayed there    12 answering question for half an hour.</b></p> <p>13     Q. Okay. Let's, again, stick just with    14 the donor organ. Am I correct that the only    15 information you gave Noah Leopold about this    16 donor organ was it's coming from an excellent    17 donor?</p> <p>18     <b>A. I don't recall the -- the conversation    19 entirely. I know that the donor told her -- I    20 mean that our transplant coordinator told her    21 that it was from increased-risk donor, and he    22 accepted that.</b></p> <p>23     Q. I'm not talking about what the    24 transplant coordinator talked with him about.    25 I'm not talking about what anybody else talked</p>	<p style="text-align: center;">Page 61</p> <p>1     <b>A. I don't recall, but I --    2 I don't recall any more than that, but    3 it was an excellent donor and continues to be.</b></p> <p>4     Q. Would it be your standard practice to    5 tell a person like Noah anything about the risks    6 of the donor organ other than "You know what,    7 this is an excellent donor?"</p> <p>8     <b>A. Well the standard practice is we have    9 to talk about DCD, if it's DCD or not DCD. This    10 donor was not DCD, it was brain dead. Whether    11 or not, you know, it's increased risk, all    12 right, it's already done by the transplant    13 coordinator and we have to -- and -- and if he    14 was hepatitis C or not hepatitis C. This donor    15 was not hepatitis C positive, so that's --    16 that's why, you know, we have to make sure that    17 we provide that information, and we did.</b></p> <p>18     Q. Okay. Back to my question.</p> <p>19     Would it have been your standard    20 practice --</p> <p>21     I know you don't remember this    22 conversation, but you know this wasn't a DCD    23 donor; right?</p> <p>24     <b>A. (Witness nodding.)</b></p> <p>25     Q. Yes? You've got to say yes for the</p>

<p style="text-align: right;">Page 62</p> <p>1 record.</p> <p>2       <b>A. Yeah, it was not.</b></p> <p>3       Q. And you know that this wasn't a --</p> <p>4       <b>A. And I already told you that already, --</b></p> <p>5       Q. You know this --</p> <p>6       <b>A. -- so it's already on the transcript.</b></p> <p>7       Q. You know that this wasn't a hepatitis C</p> <p>8       donor; right?</p> <p>9       <b>A. Yes.</b></p> <p>10      Q. So let's stick with this donor, not</p> <p>11      some other hypothetical donor. Let's stick with</p> <p>12      this donor.</p> <p>13      <b>A. Well I stick to this donor because, you</b></p> <p>14      know, as I said --</p> <p>15      MR. BRANTINGHAM: Let him get to the</p> <p>16      next question, doctor.</p> <p>17      <b>A. Yeah. But you are -- you are repeating</b></p> <p>18      the information.</p> <p>19      Q. Are you ready for me to ask a question?</p> <p>20      <b>A. Yes, sir. Go ahead.</b></p> <p>21      Q. With respect to this specific donor, in</p> <p>22      your general practice, the way that you</p> <p>23      typically do things, would you have told Noah</p> <p>24      anything about the donor organ other than it's</p> <p>25      coming from an excellent donor?</p>	<p style="text-align: right;">Page 64</p> <p>1       THE REPORTER: Okay. Off the record.</p> <p>2       (Recess taken from 2:16 p.m. to 2:21</p> <p>3       p.m.)</p> <p>4       THE VIDEOGRAPHER: We're on video.</p> <p>5       THE REPORTER: We're on the record.</p> <p>6       BY MR. THOMPSON:</p> <p>7       Q. Did you look at your operative report</p> <p>8       as part of preparing to give your deposition</p> <p>9       today, doctor?</p> <p>10      <b>A. Yes, sir.</b></p> <p>11      Q. When is the last time you looked at</p> <p>12      your operative report?</p> <p>13      <b>A. This morning.</b></p> <p>14      Q. All right. Do you remember which of</p> <p>15      the two procurement surgeons called you to talk</p> <p>16      with you about the assessment of the heart when</p> <p>17      they were still in Idaho?</p> <p>18      <b>A. I don't.</b></p> <p>19      Q. Do you know for a fact that one of them</p> <p>20      called you?</p> <p>21      <b>A. I don't. I don't know. I trust both.</b></p> <p>22      Q. When you say you trust them, you trust</p> <p>23      their assessment?</p> <p>24      <b>A. Yes.</b></p> <p>25      Q. Do you feel confident that they can</p>
<p style="text-align: right;">Page 63</p> <p>1       <b>A. I have to respond again? The only</b></p> <p>2       <b>thing that I would have told him about, DCD,</b></p> <p>3       <b>hepatitis C, and increased-risk donor, and</b></p> <p>4       <b>whether it was something controversial or not.</b></p> <p>5       <b>There wasn't any controversial in the donor.</b></p> <p>6       Q. So again, like let's not talk about</p> <p>7       some hypothetical donor that this wasn't. You</p> <p>8       told --</p> <p>9       <b>A. No, I -- I tell you.</b></p> <p>10      Q. Okay. We're going to keep at this</p> <p>11      until we get straightforward answers to my</p> <p>12      straightforward questions. We're going to go</p> <p>13      back again.</p> <p>14      With respect to this specific donor, if</p> <p>15      you were following your standard practice, would</p> <p>16      you have told Noah anything about the donor</p> <p>17      organ other than it's coming from an excellent</p> <p>18      donor?</p> <p>19      <b>A. Well in -- in this case, I wouldn't</b></p> <p>20      <b>have told anything because all the evidence was</b></p> <p>21      <b>excellent.</b></p> <p>22      Q. Let's talk about the surgery itself.</p> <p>23      MR. BRANTINGHAM: We're about an hour</p> <p>24      in. Maybe take five?</p> <p>25      MR. THOMPSON: Sure.</p>	<p style="text-align: right;">Page 65</p> <p>1       independently decide that a heart is suitable</p> <p>2       for transplantation?</p> <p>3       <b>A. That's the normal clinical practice all</b></p> <p>4       <b>over the world.</b></p> <p>5       Q. Is the normal clinical practice at Mayo</p> <p>6       for them to call you and walk you through what</p> <p>7       they're seeing, or is it for them to just make</p> <p>8       the decision that this looks good?</p> <p>9       <b>A. No, it's mandatory a phone call.</b></p> <p>10      Q. Okay. How long does the phone call</p> <p>11      usually last?</p> <p>12      <b>A. Five minutes.</b></p> <p>13      Q. What sorts of information do they</p> <p>14      generally provide you?</p> <p>15      <b>A. If there's any contraindication in the</b></p> <p>16      <b>donor; for example, if they see a tumor, for</b></p> <p>17      <b>example. They want to see how the function of</b></p> <p>18      <b>the heart, what are the hemodynamics, if -- if</b></p> <p>19      <b>they palpate any coronary disease, verify</b></p> <p>20      <b>everything that is in the computer, you know, in</b></p> <p>21      <b>the computer -- in the donor that -- there's</b></p> <p>22      <b>some information, but you have to verify it</b></p> <p>23      <b>onsite. That's the normal way.</b></p> <p>24</p> <p>25</p>

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
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18 (Pages 66 to 69)

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Q. Did you review the donor's health  
4 summary?  
5 A. Yes.  
6 Q. From UNet?  
7 A. Yes.  
8 Q. When?  
9 A. I -- I don't know if the offer was done  
10 the night before or during the day. I can't  
11 remember exactly.

12 Q. How much time would you generally spend  
13 going through the UNOS records that are made  
14 available to you?

15 A. Around a half an hour.

16 Q. Do you remember if there were other  
17 hearts that were offered to Noah that day that  
18 were just as suitable for him?

19 A. No. There wasn't any.

19 (Pages 70 to 73)

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<p style="text-align: right;">Page 74</p> <p>1 [REDACTED] 2 [REDACTED] 3 [REDACTED]</p> <p>4 Q. Okay. How long do you think Noah could 5 have waited to get a heart?</p> <p>6 A. It's -- it's --</p> <p>7     <b>You can't predict that. He could have</b> 8     <b>died next day.</b></p> <p>9 Q. Do you think he probably would have 10 died the next day if you --</p> <p>11 A. Could have happened. I've seen it many 12 times.</p> <p>13 Q. Well he survived for a week even after 14 you took his heart out and left him without a 15 heart; right?</p> <p>16 A. Yeah, because I implanted acute 17 circulatory support on him.</p> <p>18 Q. Sure. Weren't --</p> <p>19 Wouldn't there have been lots of 20 intermediate steps to help Noah's circulatory 21 function if he had continued to go downhill in 22 the week or two after the 29th if he had chosen 23 to wait?</p> <p>24 A. If he had chosen to work, let's suppose 25 that you need to do more, that will, you know,</p>	<p style="text-align: right;">Page 76</p> <p>1 end-organ dysfunction what I'm telling you, and 2 so they -- they elected to wait until the kidney 3 function, you know, could have gotten better, 4 signs that he was very sick and in cardiogenic 5 shock.</p> <p>6 Q. And it did get better in less than 24 7 hours; didn't it?</p> <p>8 A. I can't recall how were the measurement 9 of the kidney function, but normally that 10 happens over two or three days that it get 11 better, the kidney function. But he didn't have 12 normal kidney function for sure.</p> <p>13 Q. If Noah's kidney function improved over 14 the course of less than 24 hours, that would be 15 a good sign for him; wouldn't it?</p> <p>16 A. Yeah. But it would be a good sign in 17 terms of, you know, he had some recovery with 18 the circulatory support, but what it tell us 19 that he's in a very borderline situation.</p> <p>20 Q. Would you have preferred for Noah to 21 have had a combined heart-liver transplant?</p> <p>22 A. No.</p> <p>23 Q. Why not?</p> <p>24 A. Because a heart-liver transplant 25 carries a mortality between 30 to 50 percent.</p>
<p style="text-align: right;">Page 75</p> <p>1 worsen his prognosis.</p> <p>2 Q. Do you know that the other doctors who 3 have testified in this case have said Noah could 4 have survived weeks or months?</p> <p>5 A. I don't agree with that.</p> <p>6 MR. BRANTINGHAM: Foundation.</p> <p>7 Q. Okay.</p> <p>8 MR. BRANTINGHAM: Yeah.</p> <p>9 A. I don't agree with that and -- because 10 he was in cardiogenic shock. He had a right 11 heart catheterization show extremely low cardiac 12 index, so he could have died next day. 13 Moreover, he got end-organ dysfunction several 14 days before. So there was evidence of, you 15 know, kidney dysfunction and liver dysfunction, 16 so you don't want your patient to suffer more 17 organ dysfunction before transplant.</p> <p>18 Q. So if he was in such dire straits, do 19 you know why Dr. Daly didn't transplant him in 20 the week before you came on the service?</p> <p>21 A. I --</p> <p>22     The only thing that I recall -- I don't 23 recall -- recall anything about Dr. Daly. I 24 recall Dr. Spencer, that he got an offer, and he 25 has an increasing in his creatinine, so</p>	<p style="text-align: right;">Page 77</p> <p>1 Heart transplant might be two to three percent. 2 Comparative mortalities that we're talking.</p> <p>3 Q. Have you seen the email exchanges where 4 Dr. Spencer and the rest of the team were 5 actually pushing for him to get a combined 6 heart-liver transplant?</p> <p>7 A. I -- I don't remember seeing those. 8 I -- I know that the liver team, which are the 9 experts, said that he didn't need a liver 10 transplant.</p> <p>11 Q. Do you remember when you gave that 12 presentation with Dr. Friedman talking about the 13 advantages of doing a combined heart-liver 14 transplant?</p> <p>15 A. Yeah. That has some advantages related 16 to the antibodies that have been published here 17 at Mayo.</p> <p>18 Q. One of the other advantages is that you 19 avoid coagulopathy; right?</p> <p>20 A. Well that -- that, in terms of if you 21 implant the liver and it works fine, it might, 22 you know, get the -- the coagulation better, but 23 certainly not normal, because when you do a 24 heart-liver transplant there is a huge 25 derangement on the coagulation factors. So if</p>

<p style="text-align: center;">Page 78</p> <p>1       <b>you ask me what has more coagulopathy, certainly</b>      2       <b>a heart-liver, but within the heart-livers,</b>      3       <b>doing the liver first would have less</b>      4       <b>coagulopathy.</b></p> <p>5       Q. And as you said in your interview with      6       Dr. Friedman, "there's less coagulopathy, so the      7       liver is working" and "patients bleed less," and      8       that's quite an advantage. That's right; right?</p> <p>9       <b>A. It has not been demonstrated</b>      10      <b>extensively, but it's a physiologic thought.</b></p> <p>11      Q. Do you think that Noah's liver      12     dysfunction had anything to do with the bleeding      13     event you experienced in the operating room?</p> <p>14      <b>A. No, I don't think so.</b></p> <p>15      Q. Why is that?</p> <p>16      <b>A. Because we, you know, rely on the</b>      17     <b>assessment of the expert, the liver transplant</b>      18     <b>people, that his synthetic function was good</b>      19     <b>before the transplant, and that includes the</b>      20     <b>coagulation, so -- and as a doctor, what I can</b>      21     <b>see, his coagulation was good and -- but -- and</b>      22     <b>so I don't think it has nothing to do.</b></p> <p>23      Q. If his coagulation good -- was good,      24     why were you unable to get the bleeding from his      25     heart to stop?</p>	<p style="text-align: center;">Page 80</p> <p>1       <b>aorta blood, you know, that, you know, might</b>      2       <b>cause a tear on the aorta, you know. So, as I</b>      3       <b>said, we normally see a little -- little</b>      4       <b>bruising, and in this case we saw a little</b>      5       <b>bruising also. But, you know, that progressed,</b>      6       <b>you know, after the heart was transplanted, I --</b>      7       <b>and causing the significant bleeding.</b></p> <p>8       Q. Where was the bruising that you saw      9     when the heart came out of the OCS machine?</p> <p>10      <b>A. Normally there's a little bit in the --</b>      11      <b>in the fat that is around the aortic root.</b></p> <p>12      Q. And that's where it was in this case?</p> <p>13      <b>A. Yeah.</b></p> <p>14      Q. What percentage of hearts that come off      15     the OCS have bruising that looks like that?</p> <p>16      <b>A. Ninety percent.</b></p> <p>17      Q. Ninety?</p> <p>18      <b>A. Well I mean I haven't done the</b>      19     <b>statistics, but like educated guess.</b></p> <p>20      Q. In your experience.</p> <p>21      <b>A. Yes. Ninety percent.</b></p> <p>22      Q. You described the heart as being large      23     when you retrieved it from the OCS device. Was      24     it large as in it was edematous?</p> <p>25      <b>A. No, it was large in size. The -- the</b></p>
<p style="text-align: center;">Page 79</p> <p>1       <b>A. Well because it was bleeding diffusely,</b>      2       <b>you know. It's for me just a theory -- I don't</b>      3       <b>know what it was bleeding. It's first time I</b>      4       <b>have seen this, so it was bleeding from all over</b>      5       <b>the heart, so my suspicion there was, you know,</b>      6       <b>microtears on the aortic root and that</b>      7       <b>infiltrated the heart and make it bleed from</b>      8       <b>everywhere. It's a hypothesis. I don't know</b>      9       <b>really what it -- why it bled from everywhere.</b></p> <p>10      Q. That hypothesis that you just described      11     about there being microtears from the aortic      12     root, --</p> <p>13      <b>A. Uh-huh.</b></p> <p>14      Q. -- that's the best hypothesis you can      15     come up with based on your years of      16     education, --</p> <p>17      <b>A. Uh-huh.</b></p> <p>18      Q. -- training, and experience and the      19     fact that you were the one who was actually      20     there watching it bleed; right?</p> <p>21      <b>A. Yep. Yes, sir.</b></p> <p>22      Q. Where would those microscopic tears      23     have come from?</p> <p>24      <b>A. Because the OCS, you know, perfuses</b>      25     <b>blood on the aorta. So if you perfuse on the</b></p>	<p style="text-align: center;">Page 81</p> <p>1       <b>heart didn't have hypertrophy as was</b>      2       <b>demonstrated by the echocardiogram on the donor.</b>      3       <b>There was no hypertrophy. It was just large in</b>      4       <b>size.</b></p> <p>5       Q. Is it part of your usual practice to do      6     a predicted heart mass calculation prior to      7     transplant?</p> <p>8       <b>A. Not usually.</b></p> <p>9       Q. Why not?</p> <p>10      <b>A. Because we would rely on other factors,</b>      11     <b>the height, the weight, the gender of the donor,</b>      12     <b>the gender of the recipient. And, for example,</b>      13     <b>the -- the donor hearts that are 70 kilograms or</b>      14     <b>higher in weight, they usually will be adequate</b>      15     <b>for all recipients in terms of hemodynamic</b>      16     <b>performance. And then you have to assess if the</b>      17     <b>heart will fit in the chest, so we normally do</b>      18     <b>measurements on the CT scan on the donor, and</b>      19     <b>measurements on the CT scan on the recipient to</b>      20     <b>see if the heart will fit.</b></p> <p>21      Q. And you were fine --</p> <p>22      <b>A. But the -- but the ultimate test is</b>      23      <b>putting it in.</b></p> <p>24      Q. Sure. And in this case you had to make      25     some adjustments in order to get it to fit.</p>

<p style="text-align: right;">Page 82</p> <p>1       <b>A. Yep.</b></p> <p>2       Q. All right. The beginning of your 3       operative report you say, "Once I gave word that 4       the donor heart was suitable for 5       transplantation, the patient was anesthetized." 6       Would that have been after you got the call from 7       the procurement team in Idaho?</p> <p>8       <b>A. Yeah. Not --</b></p> <p>9       <b>Well in heart transplantation, there's</b> 10      <b>minimum morbidity of putting somebody under</b> 11      <b>general anesthesia, so it depends a little bit</b> 12      <b>on the situation. In his case, I waited for the</b> 13      <b>heart to be on the -- I can't recall exactly,</b> 14      <b>but most of the time I would wait for the word</b> 15      <b>that it's fine, and then if it's fine, then</b> 16      <b>general anesthesia allowing some prepping and</b> 17      <b>draping. And then we try to match the -- when</b> 18      <b>the heart arrives when the -- with the</b> 19      <b>explantation.</b></p> <p>20      Q. Sure. So make sure I've got this 21      right. Anesthetized probably shortly after you 22      got the call from Idaho --</p> <p>23      <b>A. Uh-huh.</b></p> <p>24      Q. -- that we've evaluated the heart, it 25      looks good.</p>	<p style="text-align: right;">Page 84</p> <p>1       <b>A. The -- the skin incision, we would do</b> 2       <b>it -- we anticipate the -- the estimated time of</b> 3       <b>arrival. So, you know, if it take me an hour,</b> 4       <b>an hour and a half, you know, to open,</b> 5       <b>cannulate, take me an hour and a half, so we --</b> 6       <b>when the airplane is usually on the air, then we</b> 7       <b>see what is the estimated time of arrival and</b> 8       <b>try to match it the best we can.</b></p> <p>9       Q. I understand.</p> <p>10      So the goal, in terms of timing, would 11      be you've made the incision, you've done -- 12      you've cracked the chest, you've got everything 13      cannulated, you are basically ready to remove 14      the heart when you get the call from the ground 15      in Rochester that they've landed safely.</p> <p>16      <b>A. It depends, again, on what's the</b> 17      <b>complexity. In his case, I mean we don't crack</b> 18      <b>the chest, we do a midline sternotomy.</b></p> <p>19      Q. Okay.</p> <p>20      <b>A. And so most of the time, if it's a</b> 21      <b>virgin chest, we'll be with the chest open and</b> 22      <b>cannulated, so when they land and they tell us</b> 23      <b>that the heart is fine, then it will go bypass</b> 24      <b>and take the heart out.</b></p> <p>25      Q. Got it.</p>
<p style="text-align: right;">Page 83</p> <p>1       <b>A. Okay. Yeah, likely. I can't recall</b> 2       <b>ex -- what was the timing exactly, but that's</b> 3       <b>the most common thing. In a patient like Mr.</b> 4       <b>Noah, because he -- you know, sometimes you need</b> 5       <b>more time because the -- this -- you anticipate</b> 6       <b>a complicated operation, so you would</b> 7       <b>anesthetize earlier than that.</b></p> <p>8       Q. Noah had what's known as a virgin 9       chest; right?</p> <p>10      <b>A. Yeah, he did.</b></p> <p>11      Q. I assume that you had no problems 12      whatsoever accessing his native heart and 13      explanting it?</p> <p>14      <b>A. Yeah. I had no problems that I</b> 15      <b>remember.</b></p> <p>16      Q. How long did it take?</p> <p>17      <b>A. It would take around, to explanted</b> 18      <b>it --</b></p> <p>19      <b>Well one thing is the explantation,</b> 20      <b>one -- a different thing is the -- you know,</b> 21      <b>open it up. So if you -- if you count from the</b> 22      <b>skin incision to get the heart out, an hour, an</b> 23      <b>hour and a half.</b></p> <p>24      Q. When -- when would you have made the 25      skin incision?</p>	<p style="text-align: right;">Page 85</p> <p>1       Fair to say you don't remember for sure 2       if that's what you did in this case, but based 3       on your general practice you think that's 4       probably what happened.</p> <p>5       <b>A. Yeah.</b></p> <p>6       Q. Describe for me --</p> <p>7       You write in your operative note about 8       adjusting the sutures, opening the posterior and 9       left-side pericardium to make this larger heart 10      fit.</p> <p>11      <b>A. Uh-huh.</b></p> <p>12      Q. Describe what you're talking about 13      there.</p> <p>14      <b>A. So the -- the pericardium is the</b> 15      <b>linings -- the lining of the heart. So if you</b> 16      <b>open it in the back and to the left, you get an</b> 17      <b>opening to the left chest so there's more room.</b> 18      <b>So that's what I did, I opened -- so I give more</b> 19      <b>room to the heart. And then the adjusting of</b> 20      <b>the sutures meaning, you know, what we call</b> 21      <b>compensating. When we do the suture, we take</b> 22      <b>more in one side than the other side. So if you</b> 23      <b>sort of -- if you take -- so you have something</b> 24      <b>big and something small, you will take normal</b> 25      <b>bites in the bigger one while you will take very</b></p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1     <b>close bites on the smaller one.</b>      2       Q. Okay. So obviously this was different      3       because you ended up having to take the heart      4       out. But if things had gone the way you wanted      5       them to, would the pericardium have been      6       completely stitched closed at the end of the      7       operation?      8       <b>A. No, I don't do that.</b>      9       Q. Because of swelling?      10      <b>A. No. I -- I don't like to close the</b>      11      <b>pericardium, because if you have a closed cavity</b>      12      <b>there's always some oozing of blood, so you</b>      13      <b>could have accumulation of clots and blood and</b>      14      <b>have, you know, tamponade.</b>      15       Q. Tamponade.      16       And so the pericardium would just be      17       left partially open permanently?      18       <b>A. Yes. So I, in all the cases, I</b>      19      <b>leave -- open it permanently on the front.</b>      20       Q. On the front.      21       <b>A. In this case it was additional on the</b>      22      <b>back to the left.</b>      23       Q. Because the heart was bigger than --      24       <b>A. Yes.</b>      25       Q. Okay. All right. Everything went</p>	<p style="text-align: right;">Page 88</p> <p>1       <b>A. You cannot quantify because it's</b>      2       <b>diffuse bleeding, so you can't count it.</b>      3       Q. All right. At what point in the      4       process did you begin to suspect that it was      5       these microscopic tears?      6       <b>A. When -- when there was bleeding from</b>      7       <b>all over the place, so I -- I -- I suspect that</b>      8       <b>that could have been the case.</b>      9       Q. Okay. What did you do about it?      10      <b>A. I -- I --</b>      11      You know, you are fully anticoagulated      12      when you are in that situation because you on      13      the heart-lung bypass machine, you need to do      14      that fully anticoagulated, so I -- I came off --      15      off the heart-and-lung bypass machine and I gave      16      protamine. We tried to seal those suspected      17      microscopic holes.      18       Q. And that didn't work.      19       <b>A. No, it didn't. And actually the heart,</b>      20       <b>it squeeze quite well, had normal function at</b>      21       <b>the beginning. But as it get more and more</b>      22       <b>infiltrated, the function, you know, went down.</b>      23       Q. Okay. Were you -- your assistant      24       was --      25       You had one assistant. It was a</p>
<p style="text-align: right;">Page 87</p> <p>1       according to plan until the cross-clamp was      2       removed. Am I correct about that?      3       <b>A. Yes.</b>      4       Q. Describe for us then what happened once      5       you took off the cross-clamp.      6       <b>A. So the -- the heart start becoming more</b>      7       <b>bruised overall until it start bleeding from</b>      8       <b>several spots. And we normally handle the heart</b>      9       <b>to check, you know, for bleeding in the back and</b>      10      <b>the front. So all those, when we grabbed,</b>      11      <b>that -- so we grabbed the heart, and then that</b>      12      <b>kind of broke off the epicardium, you know, the</b>      13      <b>layers or bled through there, and then that</b>      14      <b>process continue.</b>      15       Q. Was the blood infiltration spreading      16       from that location of ecchymosis near the aortic      17       root?      18       <b>A. I don't know because it was all over</b>      19      <b>the place, so I don't know.</b>      20       Q. It was all over the place by the time      21       you noticed it.      22       <b>A. Yeah.</b>      23       Q. Okay. All right. Estimate of how many      24       different places it looked like it was bleeding      25       from when you first noticed it.</p>	<p style="text-align: right;">Page 89</p> <p>1       fellow; right?      2       <b>A. Yeah.</b>      3       Q. Did you, during this time, did you      4       contact either Dr. Daly or Dr. Spencer?      5       <b>A. No, I didn't.</b>      6       Q. All right. How long did you spend      7       trying to get the bleeding under control?      8       <b>A. Several hours.</b>      9       Q. Do you think that there may have been a      10      component of DIC involved here?      11      <b>A. I -- I haven't heard about any labs</b>      12      <b>confirming or denying that. Nobody told me</b>      13      <b>anything about that.</b>      14       Q. Well after the fact I presume that you      15       were racking your brain and looking at the data      16       and trying to figure out what happened here to      17       cause this thing that I've never seen.      18       <b>A. Yeah. But, you know, I -- I'm hands</b>      19      <b>on, you know, trying to get the patient to stop</b>      20      <b>bleeding, so normally the -- the</b>      21      <b>anesthesiologist will be looking at all the</b>      22      <b>coagulation tests, and if there's anything</b>      23      <b>abnormal, they try to correct it the best they</b>      24      <b>can.</b>      25       Q. And the anesthesiologist didn't say</p>

<p style="text-align: right;">Page 90</p> <p>1 anything to you about there being a 2 coagulopathy.</p> <p>3     <b>A. Well I, you know, I knew that he had</b> 4     <b>coagulopathy because the way, you know, it was</b> 5     <b>bleeding all the time. So he had coagulopathy</b> 6     <b>as 90 percent of the heart transplant we do,</b> 7     <b>they have coagulopathy.</b></p> <p>8         Q. Yep.</p> <p>9     <b>A. So -- so we gave --</b></p> <p>10    We usually do two things. We'll give 11    blood products and we give concentrated blood 12    products, meaning like a powder of, you know, 13    clotting factors that is, you know, injected 14    intravenously. So that was tried. It was tried 15    when we give the protamine and it was tried 16    again. You know, then I, you know, had to go on 17    the heart-and-lung bypass machine and then I 18    went on -- on ECMO to give more support to the 19    heart. And then we gave more products, more 20    concentrated of blood products, and the bleeding 21    would not subside.</p> <p>22         Q. And then eventually you decided the 23    only thing left to do is take this heart out.</p> <p>24     <b>A. Yes.</b></p> <p>25         Q. Is that the first time that you have</p>	<p style="text-align: right;">Page 92</p> <p>1     <b>circulatory and gas-exchange support.</b></p> <p>2         Q. How does that setup differ from ECMO?</p> <p>3         <b>A. It's just in -- in ECMO you have the --</b> 4         <b>the heart is still in. So you have the can --</b> 5         <b>cannula, you know, on the right femoral vein and</b> 6         <b>another one here in the artery here or here.</b> 7         Actually we had that for a little while.</p> <p>8         Q. Yep.</p> <p>9         <b>A. And that's the difference, in one</b> 10         <b>there's heart, in the other one there's no</b> 11         <b>heart.</b></p> <p>12         Q. Okay. So this BiVAD setup, the BiVAD 13    is basically taking the place of the heart.</p> <p>14         <b>A. Yes.</b></p> <p>15         Q. Because without either a donated heart 16    or the explanted native heart, there was nothing 17    for things to flow through without putting in 18    the BiVAD?</p> <p>19         <b>A. Yeah. Because it, you know, it was</b> 20         <b>bleeding all over the place so, you know, my</b> 21         <b>alternatives was let the patient die on the</b> 22         <b>table or attempt a BiVAD oxygenator.</b></p> <p>23         Q. After the surgery was finished, did you 24    talk with Noah's family?</p> <p>25         <b>A. I remember talking multiple times to</b></p>
<p style="text-align: right;">Page 91</p> <p>1 left a patient without a heart?</p> <p>2     <b>A. No. The -- there was a colleague of</b> 3     <b>mine that had a bleeding -- it's called an</b> 4     <b>atrioventricular dysjunction, you know, the</b> 5     <b>atrium and the ventricle, they separated, and</b> 6     <b>then you try to put it back together. And then</b> 7     <b>we tried everything for that and it didn't work,</b> 8     <b>so we took the heart out, the patient stopped</b> 9     <b>bleeding.</b></p> <p>10         Q. Tell me about this attempt to put in a 11    BiVAD oxygenator implant.</p> <p>12         <b>A. Uh-huh.</b></p> <p>13         Q. First of all, what is it?</p> <p>14         <b>A. So it is essentially cannulas to drain</b> 15         <b>the blood. We put one cannula here on the right</b> 16         <b>femoral vein, another one here, so trying to</b> 17         <b>re-create the normal circulatory system. So</b> 18         <b>cannulas drain the blood from the veins, then</b> 19         <b>inject them from the pulmonary artery, then</b> 20         <b>coming back from the pulmonary veins, and then</b> 21         <b>drain it to another pump, and then that's going</b> 22         <b>into the outer, to the rest of the body.</b> 23         That's -- and then you inter -- in one of those 24         circuits or those pumps you'll interpose an 25         oxygenator to oxygenate the patient, so provide</p>	<p style="text-align: right;">Page 93</p> <p>1     <b>them.</b></p> <p>2         Q. Tell me what you remember.</p> <p>3         <b>A. Essentially the description that I gave</b> 4         <b>you, that the heart, after we took the</b> 5         <b>cross-clamp out, got an extensive hematoma,</b> 6         <b>started bleeding from everywhere. We tried to</b> 7         <b>fix it with all these maneuvers that I have just</b> 8         <b>told you. The same story.</b></p> <p>9         Q. Did you tell them that you suspected 10         that it was -- the cause of this was related to 11         the perfusion on the OCS machine?</p> <p>12         <b>A. Yeah, yeah. I -- I told them that.</b></p> <p>13         <b>Because they tell me, "Why -- why -- why that</b> 14         <b>would happen?" I said, "I suspect that there</b> 15         <b>might be micro -- microholes, you know, that</b> 16         <b>caused this."</b></p> <p>17         Q. How would the holes have been created, 18         with the pressure from the perfusion?</p> <p>19         <b>A. With the pressure of the perfusion.</b></p> <p>20         Q. So this is something that's never been 21         reported anywhere else in the world; true?</p> <p>22         <b>A. I -- I have not seen it myself before.</b></p> <p>23         Q. Have you heard of it?</p> <p>24         <b>A. No.</b></p> <p>25         Q. If it was the pressure from the OCS</p>

<p style="text-align: center;">Page 94</p> <p>1 machine that caused these little microholes in 2 the aortic root, why would that have never 3 happened before?</p> <p>4 <b>A. May -- maybe the --</b></p> <p>5 <b>You know, you don't know what the</b> 6 <b>resistance of the tissues of each person. Each</b> 7 <b>person is different, so maybe this one has less</b> 8 <b>resistance.</b></p> <p>9 Q. Yeah. That's kind of where I was going 10 with it. It sounds like -- it sounds like 11 whatever the problem was, it was something wrong 12 with that heart; right?</p> <p>13 MR. BRANTINGHAM: Foundation. Go 14 ahead.</p> <p>15 <b>A. That -- that could not be stated with</b> 16 <b>our current methods of diagnosis.</b></p> <p>17 Q. Your best explanation is that there was 18 something wrong with the heart.</p> <p>19 MR. BRANTINGHAM: Same objection. Go 20 ahead.</p> <p>21 <b>A. Well after the fact.</b></p> <p>22 Q. Sure. No. Absolutely.</p> <p>23 <b>A. In hindsight.</b></p> <p>24 Q. Does this event give you any concern 25 about the use of OCS for other donor hearts?</p>	<p style="text-align: center;">Page 96</p> <p>1 Have you written or are you intending 2 to write a case report or anything else about 3 this case?</p> <p>4 <b>A. Well there has been at least two</b> 5 <b>doctors in training at the Mayo Clinic that have</b> 6 <b>wanted to report this case. And I suspected it</b> 7 <b>could have legal implications, so I told them to</b> 8 <b>wait.</b></p> <p>9 Q. Help me understand that, please.</p> <p>10 <b>A. You know, because, you know, if, you</b> 11 <b>know, the -- the family, you know, would, you</b> 12 <b>know, make a claim against us, you know, we</b> 13 <b>don't want to, you know, publish it in the</b> 14 <b>newspaper.</b></p> <p>15 Q. So the reason that one would put out a 16 case report about this is so that other doctors 17 can be aware that this happened and let's try to 18 figure out how we can try to prevent it from 19 happening again; right?</p> <p>20 <b>A. Yep. But I would let the dust settle</b> 21 <b>so there's no emotional decisions taken.</b></p> <p>22 Q. No, no. Let's stick with my question 23 though.</p> <p>24 The reason that stuff gets published in 25 the medical literature is so that the medical</p>
<p style="text-align: center;">Page 95</p> <p>1 <b>A. Well it gives me a concern, of course.</b> 2 <b>You know, we remember our bad experiences, so --</b></p> <p>3 Q. I'm talking about, though, specifically 4 with respect to OCS. So the best explanation 5 you've been able to come up with this is that 6 there was something about the pressure on the 7 OCS machine perfusing the aortic root that 8 caused little microperforations that led to this 9 disastrous --</p> <p>10 <b>A. Yeah.</b></p> <p>11 Q. -- transplant attempt. Does that give 12 you pause in using the OCS in the future?</p> <p>13 <b>A. Well but I have to see the bulk of my</b> 14 <b>experience with OCS. So I have been able to</b> 15 <b>transplant successfully many, many patients with</b> 16 <b>the OCS. So it's important not to be guided</b> 17 <b>emotionally, but be guided scientifically and</b> 18 <b>see if it would happen ever again.</b></p> <p>19 Q. Now there have been a number of 20 studies, and there are ongoing studies, about 21 the OCS; true?</p> <p>22 <b>A. (Witness nodding.)</b></p> <p>23 Q. Yes? You got to --</p> <p>24 <b>A. Yes.</b></p> <p>25 Q. -- say yes.</p>	<p style="text-align: center;">Page 97</p> <p>1 community can benefit from sort of the high of 2 mind; right?</p> <p>3 <b>A. That's one of the benefits.</b></p> <p>4 Q. Right.</p> <p>5 And specifically, with respect to this 6 incident, it could have implications for the OCS 7 if your hypothesis is true; right?</p> <p>8 <b>A. Yeah.</b></p> <p>9 Q. And some of your colleagues want to 10 write a case report about this case to put it 11 out there into the medical literature to get 12 other people thinking about it in order to 13 advance science and patient safety; right?</p> <p>14 <b>A. Yeah. We likely will.</b></p> <p>15 Q. But you're telling me that Mayo has 16 elected not to do that --</p> <p>17 <b>A. No. I told them not to do it yet.</b></p> <p>18 Q. Okay. You told them not to do it yet 19 because you're worried that there may be legal 20 ramifications.</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. And legal ramifications are you don't 23 want there to be a case report that's going to 24 be out there in the newspaper.</p> <p>25 <b>A. Well I -- I don't want bad publicity</b></p>

25 (Pages 94 to 97)

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<p style="text-align: center;">Page 98</p> <p>1     <b>certainly.</b></p> <p>2       Q. Why not?</p> <p>3       <b>A. Because that will affect Mayo and other</b></p> <p>4       <b>patients -- will affect other patients mainly.</b></p> <p>5       <b>They would, you know, not receive the care that</b></p> <p>6       <b>they need.</b></p> <p>7       Q. So you're withholding potentially</p> <p>8       important scientific information in order to</p> <p>9       avoid bad -- bad publicity for Mayo.</p> <p>10      <b>A. No, sir.</b></p> <p>11      Q. Okay. Have you reported this to</p> <p>12      TransMedics?</p> <p>13      <b>A. No.</b></p> <p>14      Q. Why not?</p> <p>15      <b>A. Because we wanted the dust settled</b></p> <p>16      <b>before tell other people.</b></p> <p>17      Q. How long are you waiting for the dust</p> <p>18      to settle?</p> <p>19      <b>A. Until we're finished with your claim.</b></p> <p>20      Q. Okay. So hold on. Your best</p> <p>21      hypothesis is that there was something about</p> <p>22      this OCS machine's perfusion that caused a</p> <p>23      catastrophic loss of this donor heart. Yes?</p> <p>24      That's your best hypothesis.</p> <p>25      <b>A. Yes.</b></p>	<p style="text-align: center;">Page 100</p> <p>1       MR. BRANTINGHAM: Go ahead, you can</p> <p>2       answer.</p> <p>3       Q. Okay. So what am I missing? Tell me</p> <p>4       about this conversation.</p> <p>5       <b>A. No. There's -- there's -- there's, you</b></p> <p>6       <b>know, the International Society of Heart and</b></p> <p>7       <b>Lung Transplantation meeting, and then we see</b></p> <p>8       <b>all the people there, you know, including --</b></p> <p>9       <b>including the TransMedics people because they</b></p> <p>10      <b>present their technology, so they told me there</b></p> <p>11      <b>was a lawyer looking for the records.</b></p> <p>12      Q. Who told you?</p> <p>13      <b>A. I don't remember.</b></p> <p>14      Q. Somebody from TransMedics.</p> <p>15      <b>A. Yeah.</b></p> <p>16      Q. And it was while you were at the</p> <p>17      International Heart/Lung Transplantation Society</p> <p>18      meeting?</p> <p>19      <b>A. Yes.</b></p> <p>20      Q. Where?</p> <p>21      <b>A. In Prague.</b></p> <p>22      Q. In Prague?</p> <p>23      When?</p> <p>24      <b>A. In April.</b></p> <p>25      Q. Have you talked to anybody else about</p>
<p style="text-align: center;">Page 99</p> <p>1       Q. You certainly know that TransMedics</p> <p>2       would like to know about this.</p> <p>3       <b>A. They already know.</b></p> <p>4       Q. How?</p> <p>5       <b>A. Because you already reached to them.</b></p> <p>6       Q. Right. I reached to them to get</p> <p>7       medical records.</p> <p>8       How do you know that, by the way?</p> <p>9       <b>A. They -- they told me. You know, I was</b></p> <p>10      <b>told that -- that -- I don't remember who it was</b></p> <p>11      <b>that told me that you were asking about the --</b></p> <p>12      <b>the records.</b></p> <p>13      Q. Oh, somebody at TransMedics?</p> <p>14      <b>A. Yeah, likely.</b></p> <p>15      Q. Got it.</p> <p>16      <b>A. Filtered.</b></p> <p>17      Q. So I called to get --</p> <p>18      I contacted TransMedics to get records,</p> <p>19      and TransMedics called you and said --</p> <p>20      <b>A. No.</b></p> <p>21      Q. -- "Hey, just so you know, some</p> <p>22      lawyer's poking around."</p> <p>23      MR. BRANTINGHAM: Object to the form of</p> <p>24      the question.</p> <p>25      <b>A. No.</b></p>	<p style="text-align: center;">Page 101</p> <p>1       this?</p> <p>2       <b>A. No.</b></p> <p>3       Q. Nobody?</p> <p>4       <b>A. I think I told my -- my chairman. I</b></p> <p>5       <b>think I -- for some reason I had to tell my</b></p> <p>6       <b>chairman, I don't know why, and the director of</b></p> <p>7       <b>the transplant center here, but other than that.</b></p> <p>8       Q. Have you talked with any of the people</p> <p>9       who are currently doing research on the OCS?</p> <p>10      <b>A. Like who?</b></p> <p>11      Q. Well any of your colleagues, people at</p> <p>12      Duke or people at Mass General or people</p> <p>13      anywhere else?</p> <p>14      <b>A. No. No. I was requested not to talk</b></p> <p>15      <b>to anybody. And I didn't ask this TransMedics</b></p> <p>16      <b>thing that I was told. They told me. I didn't</b></p> <p>17      <b>ask in the IHLT meeting. They told me that, so</b></p> <p>18      <b>I didn't ask. And so I haven't wanted to talk</b></p> <p>19      <b>to anybody --</b></p> <p>20      Q. Okay.</p> <p>21      <b>A. -- about it.</b></p> <p>22      Q. So the people from TransMedics told you</p> <p>23      there's a lawyer asking questions.</p> <p>24      <b>A. Yeah.</b></p> <p>25      Q. Did you tell them anything more about</p>

<p style="text-align: right;">Page 102</p> <p>1 the case?</p> <p>2     <b>A. No.</b></p> <p>3     Q. Did you just -- you say, "I've been</p> <p>4     advised to not talk about it?"</p> <p>5     <b>A. I -- I said "Okay" and I walk away.</b></p> <p>6     Q. You said o --</p> <p>7     <b>A. "Okay" --</b></p> <p>8     Q. And walked away.</p> <p>9     <b>A. And then I walk away.</b></p> <p>10    Q. Did the person from TransMedics think</p> <p>11    it was strange that you just said "Okay" and</p> <p>12    walked away?</p> <p>13    MR. BRANTINGHAM: Foundation.</p> <p>14    Q. Did they seem like they thought it was</p> <p>15    strange?</p> <p>16    <b>A. No, no, because you have very short</b></p> <p>17    <b>conversations normally in these meetings. You</b></p> <p>18    <b>talk to somebody and go, talk to somebody and</b></p> <p>19    <b>go. It's normal. I don't want to be rude with</b></p> <p>20    <b>people, so I -- I don't tell them, you know,</b></p> <p>21    <b>"Shut up," you know. I don't -- you know, I</b></p> <p>22    <b>don't want to talk to anybody about it. So I</b></p> <p>23    <b>was told, I said "Okay," I walk away.</b></p> <p>24    Q. Why haven't you talked with any of your</p> <p>25    cardiac transplant surgery colleagues about this</p>	<p style="text-align: right;">Page 104</p> <p>1     Q. You got to answer my question.</p> <p>2     <b>A. Yeah. There wasn't, but I suspected</b></p> <p>3     <b>there could have been.</b></p> <p>4     Q. You suspected that maybe there was</p> <p>5     going to be a claim as far back as September of</p> <p>6     2023?</p> <p>7     <b>A. Yes.</b></p> <p>8     Q. And so you made the independent</p> <p>9     decision that, "Well, because I think there may</p> <p>10    be the possibility of a legal claim, I'm keeping</p> <p>11    this under wraps and I'm not telling anybody."</p> <p>12    MR. BRANTINGHAM: Object to the form of</p> <p>13    the question.</p> <p>14    <b>A. Yeah. I -- I prefer not to talk to --</b></p> <p>15    <b>again until, you know, I'm sure that there was</b></p> <p>16    <b>not going to be any claim.</b></p> <p>17    Q. And then October passed and November</p> <p>18    passed and December passed and you didn't hear</p> <p>19    anything about a claim; right?</p> <p>20    <b>A. No, I think I heard it in February.</b></p> <p>21    Q. No. So we'll get to that.</p> <p>22    September, October, November, December,</p> <p>23    four months you heard nothing about a claim and</p> <p>24    you still kept it under wraps, didn't report it</p> <p>25    to the FDA, didn't talk to TransMedics about it,</p>
<p style="text-align: right;">Page 103</p> <p>1 case outside of Mayo?</p> <p>2     <b>A. In other -- in other centers you mean?</b></p> <p>3     Q. Outside of Mayo.</p> <p>4     <b>A. Because I was recommended not to talk</b></p> <p>5     <b>to anybody about the case. I think this was in</b></p> <p>6     <b>February. I believe so.</b></p> <p>7     MR. BRANTINGHAM: Well don't get into</p> <p>8     our communications, doctor, but your best memory</p> <p>9     in response to Mr. Thompson's questions is all</p> <p>10    you can give him.</p> <p>11    <b>A. I --</b></p> <p>12    MR. BRANTINGHAM: Let's have another</p> <p>13    question because I'm unsure even what the</p> <p>14    question is right now.</p> <p>15    Q. Did you report this to the FDA?</p> <p>16    <b>A. No, I haven't reported it to FDA.</b></p> <p>17    Q. Why not?</p> <p>18    <b>A. Because, you know, I was told to not</b></p> <p>19    <b>talk to anybody, --</b></p> <p>20    Q. Well --</p> <p>21    <b>A. -- legal matters.</b></p> <p>22    Q. Right. But there were no --</p> <p>23    There was no legal issue in September</p> <p>24    of 2023; right? Right?</p> <p>25    THE REPORTER: Your answer?</p>	<p style="text-align: right;">Page 105</p> <p>1     didn't talk to anybody outside the little Mayo</p> <p>2     cocoon.</p> <p>3     MR. BRANTINGHAM: Object to the form of</p> <p>4     the question. Go ahead.</p> <p>5     <b>A. Yes. I believe that's a short time in</b></p> <p>6     <b>clinical terms.</b></p> <p>7     Q. Okay. Did you think about reporting</p> <p>8     it?</p> <p>9     <b>A. Well, yeah, after I'm sure that there's</b></p> <p>10    <b>no legal claim.</b></p> <p>11    Q. Who are your colleagues here who want</p> <p>12    to write a case report about it?</p> <p>13    <b>A. The transplant fellow, I believe, and</b></p> <p>14    <b>other one I think it was a cardiology fellow --</b></p> <p>15    <b>no, no -- an intensivist fellow, but I don't</b></p> <p>16    <b>even know his name. I mean I know the name of</b></p> <p>17    <b>the cardiac fellow.</b></p> <p>18    Q. When did they tell you that they want</p> <p>19    to write a case report about this?</p> <p>20    <b>A. I don't remember.</b></p> <p>21    Q. Before February?</p> <p>22    <b>A. I don't --</b></p> <p>23    <b>I suspect December, January, I suspect.</b></p> <p>24    <b>I can't -- can't recall.</b></p> <p>25    Q. And you told them "Let's just kind of</p>

<p style="text-align: right;">Page 106</p> <p>1 wait for the dust to settle and see if there's a 2 legal claim."</p> <p><b>A. Yes.</b></p> <p>Q. Do you know that there is a Patient Safety Incident Reporting Guideline at Mayo?</p> <p><b>A. No, I don't.</b></p> <p>Q. Do you know that there is an online incident reporting tool available to the transplant team at Mayo?</p> <p><b>A. No. I -- I -- I suspect that there could be something to report, but -- but -- but I -- I haven't used it ever, so I don't know.</b></p> <p>Q. Do you know what the MAUDE database is?</p> <p><b>A. No.</b></p> <p>Q. Do you know that the FDA maintains a database that allows doctors to report incidents with medical devices so that it can raise awareness throughout the medical community?</p> <p><b>A. It would have been already published if it wouldn't been a claim, and then everybody will be ed -- it would have been educated. But because there was a claim, there's no education.</b></p> <p>Q. None of that was my question. I'm going to go back to my question.</p> <p><b>A. It is -- it is my answer.</b></p>	<p style="text-align: right;">Page 108</p> <p>1 ensure you don't talk about our communications, 2 doctor, or --</p> <p>3 THE WITNESS: Okay.</p> <p>4 MR. BRANTINGHAM: -- the communications 5 with Mayo Legal.</p> <p>6 Q. But I think you told me before that one 7 of the reasons why you didn't talk about it, 8 even before the legal team got involved, was 9 because you didn't want bad publicity for the transplant program.</p> <p><b>A. Yeah, I think that's accurate.</b></p> <p>11 MR. THOMPSON: Let's take a break. 12 THE REPORTER: Off the record. 13 (Recess taken from 3:11 p.m. to 3:35 14 p.m.) 15 THE VIDEOGRAPHER: We're on video. 16 THE REPORTER: We're on the record. 17 MR. BRANTINGHAM: Before you proceed, 18 I -- pursuant to the protective order, I want to 19 designate this transcript as confidential. 20 MR. THOMPSON: All right. Based on? 21 MR. BRANTINGHAM: Based on all of the 22 PHI, all of the sensitive health information in 23 it, based on the totality of everything we're 24 talking about.</p>
<p style="text-align: right;">Page 107</p> <p>1 MR. BRANTINGHAM: Wait for the 2 question, doctor.</p> <p>3 Q. Are you familiar with the fact that the 4 FDA has a publicly-accessible database that 5 allows doctors to report problems with devices?</p> <p><b>A. No, I'm not aware. What is the particular database? I suspect that there's a reporting instrument, but I -- I don't know the specifics.</b></p> <p>Q. Would you like to report this catastrophe to somebody outside of Mayo?</p> <p>MR. BRANTINGHAM: Object to the form.</p> <p><b>A. I -- I would like to publish the case and at the same time report it to the FDA.</b></p> <p>Q. And you're planning to do that, but just you're going to wait until this lawsuit's over.</p> <p><b>A. Yes.</b></p> <p>Q. Because you don't want there to be bad publicity for your transplant program.</p> <p>MR. BRANTINGHAM: Object to the form of the question. Go ahead.</p> <p><b>A. Because I -- I have been advised not to talk to anybody by my legal team.</b></p> <p>MR. BRANTINGHAM: And -- and just</p>	<p style="text-align: right;">Page 109</p> <p>1 MR. THOMPSON: Okay.</p> <p>2 BY MR. THOMPSON:</p> <p>3 Q. All right. Doctor, despite this event 4 that you're planning to someday report to the 5 FDA and TransMedics, Mayo is continuing full 6 bore using the OCS; right?</p> <p><b>A. Yes.</b></p> <p>8 MR. BRANTINGHAM: Object to the form of 9 the question. Go ahead, doctor.</p> <p><b>A. Yes, we are using OCS for heart transplantation.</b></p> <p>Q. You haven't reduced your use of OCS since this event; have you?</p> <p><b>A. No, I have not.</b></p> <p>Q. You've increased your use of OCS.</p> <p><b>A. No. I haven't done the statistics, but it looks like around the same.</b></p> <p>Q. When you went to Prague for that International Society meeting, you presented on TransMedics data; right?</p> <p><b>A. Yes.</b></p> <p>Q. Did TransMedics provide you a stipend?</p> <p><b>A. No.</b></p> <p>Q. They didn't cover any of your travel expenses, nothing.</p>

<p style="text-align: right;">Page 110</p> <p>1       <b>A. No.</b>      2       Q. All right. You presented on --      3              Part of what you presented on was      4              information about TransMedics NOP program;      5              right?      6       <b>A. OP?</b>      7       Q. NOP? Their National --      8       <b>A. Oh, the National Organ --</b>      9       Q. National OCS Program.      10      <b>A. Not -- not quite the same.</b>      11       Q. Okay. Let me ask it a different way.      12              You know about TransMedics' National      13              OCS Program; right?      14       <b>A. Yeah. I have not used it.</b>      15       Q. No, I know. But you know what it is?      16       <b>A. Yes.</b>      17       Q. What it is?      18       <b>A. Which is that the transplant</b>      19       <b>procurement surgeons from TransMedics will go</b>      20       <b>and fly out and retrieve an organ on the OCS to</b>      21       <b>the transplant center to get transplanted.</b>      22       Q. TransMedics has their own planes;      23              right?      24       <b>A. Yes.</b>      25       Q. They've got dedicated people whose only</p>	<p style="text-align: right;">Page 112</p> <p>1       Wouldn't outcomes be better, presum --      2              Well let me ask you this question: Do      3              you agree with the basic concept in medicine      4              that the more experienced you are, in general,      5              the better you are at doing things?      6       <b>A. Yes.</b>      7       Q. One of the reasons why you're trying to      8              bulk up the transplant numbers in the Mayo heart      9              transplant program; right?      10       <b>A. Yes.</b>      11       Q. So wouldn't it stand to reason that if      12              you've got OCS specialists who literally all      13              they are doing day in and day out is doing OCS      14              organ procurement, that would lead to improved      15              clinical outcomes?      16       <b>A. No, sir.</b>      17       MR. BRANTINGHAM: Foundation.      18       <b>A. That's wrong.</b>      19       Q. Are you familiar with TransMedics'      20              statistics on clinical outcomes for facilities      21              that are using their people as opposed to using      22              other people?      23       <b>A. No, I don't.</b>      24       Q. You haven't even bothered to review      25              their statistics as part of deciding whether</p>
<p style="text-align: right;">Page 111</p> <p>1       job is to do organ procurement for OCS      2              transport; right?      3       <b>A. Yes.</b>      4       Q. Why doesn't Mayo use that service?      5       <b>A. Be --</b>      6              <b>There's two reasons. Because one</b>      7              <b>thing, it's more expensive, so I want to, you</b>      8              <b>know, be as inexpensive as possible. And the</b>      9              <b>second reason is they are -- the surgeons are,</b>      10             <b>you know, TransMedics' employees, so I see a</b>      11             <b>conflict of interest. So I prefer my own people</b>      12             <b>to assess the organs and put them on the device</b>      13             <b>if needed.</b>      14       Q. Doesn't it make sense to you to have      15              the most experienced people possible running      16              this complicated machine?      17       <b>A. Yes, but with no conflict of interest.</b>      18       Q. How is it a conflict of interest to      19              have the most experienced people operating a      20              machine that they know better than anyone?      21       <b>A. Yeah. Because their salary depend on</b>      22             <b>the company, so I want people with no salary</b>      23             <b>from the company.</b>      24       Q. How does that --      25       You got to help me understand that.</p>	<p style="text-align: right;">Page 113</p> <p>1       you're going to use their TransMedics program?      2       <b>A. I don't see -- I --</b>      3              <b>I don't know where are the -- the</b>      4              <b>centers that, you know, doing their own at this</b>      5              <b>point in time.</b>      6       Q. Now your hypothesized problem with this      7              heart was that there was something about the way      8              that the blood was being perfused into the      9              aortic root through the OCS system; right?      10       <b>A. No, not -- not in the way. I -- I</b>      11              <b>suspect that, you know, all the hemodynamics</b>      12              <b>parameters are good, so I suspect there is</b>      13              <b>something in -- in the tissue of the -- the</b>      14              <b>heart that cannot be assessed with the current</b>      15              <b>diagnostic methods that, you know, made them</b>      16              <b>weakened to filtrate the blood.</b>      17       Q. Got it. That this heart that came from      18              the meth addict, intracranial hemorrhage,      19              alcoholic, cigarette smoker, convicted felon      20              with all those drugs in his system, maybe there      21              was something wrong with his heart.      22       MR. BRANTINGHAM: I'll object to the      23              form of the question. If you can an -- go ahead      24              if you're --      25       <b>A. Well looking -- looking back, because</b></p>

<p style="text-align: right;">Page 114</p> <p>1   <b>there were this bleeding and you could think 2   that there's -- there was something wrong with 3   the heart, but with all the diagnostic tools 4   that we currently have, the -- the heart was 5   excellent.</b></p> <p>6   Q. Well you thought the heart was 7   excellent, but now we know, in retrospect, your 8   best hypothesis is there was something wrong 9   with that heart; right?</p> <p>10   <b>A. The --</b></p> <p>11   <b>No. No. The heart was excellent by 12   the, you know, criteria of the International 13   Society of Heart and Lung Transplantation, you 14   know, published last year. It checked all the 15   boxes for an optimal, excellent heart.</b></p> <p>16   Q. Wasn't my question though.</p> <p>17   Your best hypothesis is there was 18   something with the tissue in that particular 19   heart that made it not able to withstand the 20   perfusion pressures on the OCS machine like 21   every other heart you've ever had on the OCS 22   machine did; right?</p> <p>23   <b>A. Yes, but I couldn't diagnose that.</b></p> <p>24   Q. I know you couldn't diagnose that. But 25   your best hypothesis is there was something</p>	<p style="text-align: right;">Page 116</p> <p>1   <b>A. Yeah. I don't know.</b></p> <p>2   Q. Do you know how many OCS runs the OCS 3   specialist from Mayo who was responsible for the 4   perfusion on this heart had been on?</p> <p>5   <b>A. I don't. I haven't counted.</b></p> <p>6   Q. Would it surprise you to know that she 7   testified yesterday that it was probably 8   something like six or seven at the time she did 9   this run?</p> <p>10   <b>A. I think there were two normally. I 11   think there were two perfusionists normally.</b></p> <p>12   Q. Okay.</p> <p>13   <b>A. So you have the count. I don't know 14   the count of how many have they gone.</b></p> <p>15   Q. And as for whether the OCS specialists 16   in the NOP Program are orders of magnitude more 17   experienced than the Mayo people, you just don't 18   know.</p> <p>19   <b>A. No. I -- I don't know. But -- but 20   again, they have a conflict of interest. So we 21   don't want conflict of interest in the decisions 22   of -- in heart transplantation.</b></p> <p>23   Q. I'm still having a hard time 24   understanding the conflict of interest as it 25   applies to patient outcomes. Are you suggesting</p>
<p style="text-align: right;">Page 115</p> <p>1   wrong with that heart; right?</p> <p>2   <b>A. Yep.</b></p> <p>3   MR. BRANTINGHAM: Object to the form. 4   Go ahead.</p> <p>5   <b>A. Something that was microscopic and not 6   see it with the current diagnosis test again.</b></p> <p>7   Q. Well your people didn't see it. We 8   don't know if maybe the more experienced 9   TransMedics people wouldn't have seen it; do we?</p> <p>10   MR. BRANTINGHAM: Foundation.</p> <p>11   <b>A. That's very unlikely.</b></p> <p>12   Q. Why?</p> <p>13   <b>A. Because my people are -- are trained 14   and they work in an academic surgical center. 15   TransMedics is not -- doesn't have a Department 16   of Cardiovascular Surgery. So you would think 17   that you would like to have heart surgery, you 18   would go to the Department of Cardiovascular 19   Surgery, not to a company.</b></p> <p>20   Q. Do you know how many OCS procurements 21   the TransMedics NOP Program have done?</p> <p>22   <b>A. I don't.</b></p> <p>23   Q. So you don't know how many orders of 24   magnitude more they've done than your people at 25   Mayo.</p>	<p style="text-align: right;">Page 117</p> <p>1   that because these people are paid by 2   TransMedics, they somehow have an incentive to 3   not do as good of a job?</p> <p>4   <b>A. No, they try to do a good job, as any 5   human being likes to do, but their incentive is 6   different. You know, they are not part of the 7   Department of Surgery, so they are not doing 8   surgery all the time. That is a problem. They 9   are just doing procurements. So in any 10   unexpected thing that can happen, it will be 11   more difficult to, you know, handle because they 12   are not in everyday surgery. And then their 13   incentive is to do more hearts or more lungs. 14   They are -- you know, they do not have an 15   incentive for the outcome as I do. I have to 16   respond to the patient and the family --</b></p> <p>17   Q. So you're telling --</p> <p>18   <b>A. -- or my institution, et cetera.</b></p> <p>19   Q. So your testimony is that having people 20   going and procuring these organs, who all they 21   do is procure organs rather than actually doing 22   surgery, is a problem.</p> <p>23   <b>A. Yes.</b></p> <p>24   Q. You know that Dr. Altarabsheh literally 25   only procures organs; right?</p>

<p style="text-align: right;">Page 118</p> <p>1       <b>A. No.</b>  2            MR. BRANTINGHAM: Object to form.  3       <b>A. No, no. He doesn't.</b>  4            Q. That was his testimony under oath.  5       <b>A. No. He doesn't.</b>  6            MR. BRANTINGHAM: Hang on. Just hang  7           on. That's not a question.  8           Q. Are --  9           Is it your testimony that you think  10          that Dr. Salah Altarabsheh does something else  11          for Mayo other than procure organs?  12       <b>A. Yes.</b>  13          Q. Would it surprise you to know that his  14          testimony under oath on Monday was that that  15          literally is all he does for Mayo?  16          MR. BRANTINGHAM: Object to foundation.  17       <b>A. Well that would have been wrong because</b>  18       <b>I have seen him in the -- in the OR working.</b>  19          Q. Doing what?  20       <b>A. Heart surgery.</b>  21          Q. What kind of heart surgery?  22       <b>A. Helping in heart surgery, assisting.</b>  23          Q. Helping. What does he do when he's  24          helping?  25       <b>A. Like any doctor helps in surgery, you</b></p>	<p style="text-align: right;">Page 120</p> <p>1       <b>A. Yes. When you go and discuss a case in</b>  2       <b>a conference, that's a technical skill --</b>  3           Q. Got it.  4       <b>A. -- where you have to learn, you know,</b>  5       <b>how to do things and what's the most appropriate</b>  6       <b>treatment.</b>  7           Q. Let's talk about what he's doing in  8           surgery. I want to make sure I get a complete  9           list of the things that you say you've seen Dr.  10          Altarabsheh do in the operating room at Mayo.  11          You said he helps with exposure, sometimes he  12          holds stitches. What else have you seen him do  13          in the operating room?  14       <b>A. He helps from the surgery from start to</b>  15       <b>finish, open the chest, close the chest.</b>  16          Q. That would be helping with exposure;  17          right?  18       <b>A. Yes.</b>  19          Q. So let's --  20       <b>A. That's surgery.</b>  21          Q. Yeah. No, I know.  22       <b>A. What -- what else -- what else are you</b>  23       <b>asking about?</b>  24          Q. I'm -- I'm not a heart surgeon and I'm  25          not the one --</p>
<p style="text-align: right;">Page 119</p> <p>1       <b>know, goes in front of the primary surgeon and</b>  2       <b>helps expose, hold the stitches, aspirate, so on</b>  3       <b>and so forth.</b>  4          Q. Okay. I want to get a list of all the  5          things that Dr. Altarabsheh does that makes him  6          more competent than these TransMedics people.  7          He helps with exposure sometimes; right?  8       <b>A. Yeah.</b>  9          Q. Okay. He holds stitches. Is that what  10         you said?  11       <b>A. Yeah. So he's a first assist in</b>  12       <b>surgery.</b>  13          Q. Yeah. What else have you seen him do?  14       <b>A. Well he goes to the conferences.</b>  15       <b>There's morbidity and mortality conferences, so</b>  16       <b>he discuss the cases here -- here in the -- in</b>  17       <b>the board reviews, in knowledge-review content,</b>  18       <b>all the academic work that is done at the Mayo</b>  19       <b>Clinic Department of Cardiovascular Surgery.</b>  20          Q. Yeah. We're going to stick just with  21          skills for now, so --  22       <b>A. That's a skill, sir.</b>  23          Q. Technical skills.  24       <b>A. Those are technical skills.</b>  25          Q. Attending conferences?</p>	<p style="text-align: right;">Page 121</p> <p>1       <b>A. Well --</b>  2          Q. Just hold on.  3          MR. BRANTINGHAM: Hang on. Yeah,  4          just --  5          Q. You asked me a question. Now I'm going  6          to try to provide you information to clarify  7          what I'm trying to get at here.  8          You're the one who testified that the  9          people in the TransMedics NOP Program aren't as  10         competent as your Mayo people because all they  11         do is procure organs. I pointed out to you that  12         Dr. Altarabsheh testified that all he does is  13         procure organs. And now you're saying that's  14         not true, I've seen him do stuff in the OR.  15       <b>A. Correct.</b>  16          Q. So now I'm trying to get a complete  17          list from you of the things that you have seen  18          Dr. Altarabsheh do in a Mayo operating room, and  19          so far we've got he helps with exposure and  20          sometimes he holds stitches. What else does he  21          do in the operating room?  22       <b>A. Suctions.</b>  23          MR. BRANTINGHAM: Go ahead.  24       <b>A. He separates.</b>  25          Q. Separates what?</p>

<p style="text-align: right;">Page 122</p> <p>1       <b>A. The -- the tissues. He does traction,</b>  2       <b>countertraction.</b></p> <p>3       Q. Is there --</p> <p>4       <b>A. All -- all the scope of heart surgery.</b></p> <p>5       Q. Is there anything that Dr. Altarabsheh  6       does that you wouldn't let a second-year  7       resident do?</p> <p>8       <b>A. No, he can do way more than that.</b></p> <p>9       Q. Well you let second-year residents help  10      with exposure; right?</p> <p>11      <b>A. No, sir.</b></p> <p>12      Q. No?</p> <p>13      <b>A. No.</b></p> <p>14      Q. Okay. How experienced does somebody  15      have to be in their training before you'll let  16      them help with exposure?</p> <p>17      <b>A. They usually a PGY-7, -8, or -9, so</b>  18      <b>seven years, eight years, or nine years of</b>  19      <b>training.</b></p> <p>20      Q. Got it. Got to be in the seventh year  21      of your residency.</p> <p>22      How about holding stitches?</p> <p>23      <b>A. Holding stitches, it could be even</b>  24      <b>complicated for a heart surgeon to hold properly</b>  25      <b>a stitch.</b></p>	<p style="text-align: right;">Page 124</p> <p>1       their residency?</p> <p>2       <b>A. In being in heart surgery in general,</b>  3       <b>residency, residency practice.</b></p> <p>4       Q. Before they can provide suction.</p> <p>5       <b>A. Yes. If you do suction in an</b>  6       <b>appendectomy then, you know, an intern might be</b>  7       <b>do it. But you do a complicated Fontan</b>  8       <b>operation, you need someone with a lot of years</b>  9       <b>of experience to provide suction.</b></p> <p>10      Q. Okay. Holding traction, how  11      experienced --</p> <p>12      <b>A. Same, ten or more years. The more the</b>  13      <b>better.</b></p> <p>14      Q. I'm -- I'm trying to understand what  15      you mean, though, when you say "ten or more  16      years." Do you mean ten or more years out of  17      medical school, or ten or more years out of your  18      fellowship?</p> <p>19      <b>A. After -- after medical school, general</b>  20      <b>surgery, cardiothoracic training, independent</b>  21      <b>practice, et cetera. Everything.</b></p> <p>22      MR. THOMPSON: Gotcha. I'm going to go  23      ahead and end there, and I'm sure Mr.  24      Brantingham's got some questions he wants to ask  25      you.</p>
<p style="text-align: right;">Page 123</p> <p>1       Q. Okay. How far does somebody have to be  2       in their training in the Mayo program before  3       you'll let them hold stitches?</p> <p>4       <b>A. In the Mayo program?</b></p> <p>5       Q. Well you teach Mayo doctors; right?</p> <p>6       <b>A. Well I teach Mayo -- Mayo doctors, but</b>  7       <b>they already have learned in general surgery how</b>  8       <b>to hold the stitches in simple operations. In</b>  9       <b>complicated operations, I tell them how to do</b>  10      <b>it.</b></p> <p>11      Q. Understood.</p> <p>12      <b>A. But it's not the only background that</b>  13      <b>Dr. Salah Altarabsheh has.</b></p> <p>14      Q. Okay. Providing suction. How  15      experienced does a doctor have to be to provide  16      suction?</p> <p>17      <b>A. Very experienced.</b></p> <p>18      Q. Very experienced?</p> <p>19      <b>A. Yes.</b></p> <p>20      Q. How experienced?</p> <p>21      <b>A. In heart surgery.</b></p> <p>22      Q. How experienced?</p> <p>23      <b>A. Years. More than ten years of heart</b>  24      <b>surgery.</b></p> <p>25      Q. More than 10 years out of</p>	<p style="text-align: right;">Page 125</p> <p>1       MR. BRANTINGHAM: Yeah. I've got a  2       couple questions, doctor. Bear with me one  3       moment. Sorry.</p> <p>4       <b>EXAMINATION</b>  5       <b>BY MR. BRANTINGHAM:</b></p> <p>6       Q. I want to ask about the topics that Mr.  7       Thompson was asking you about with regard to  8       publishing -- or about this case or reporting  9       some issue to the FDA or some other body. Do  10      you --</p> <p>11      <b>A. Uh-huh.</b></p> <p>12      Q. -- remember those questions?</p> <p>13      My question for you is: Number one,  14      there are -- are there internal procedures  15      within Mayo or -- and/or within your department  16      to review adverse events or complications?</p> <p>17      <b>A. Yes, we have the morbidity and</b>  18      <b>mortality conferences and the quap -- I mean</b>  19      <b>quality conferences to review the --</b></p> <p>20      Q. Okay.</p> <p>21      <b>A. -- cases and look at the overall</b>  22      <b>statistics.</b></p> <p>23      Q. Okay. And I -- I'm not going to ask  24      you to talk about any of the conclusions of the  25      process because, as you understand, those are --</p>

<p style="text-align: right;">Page 126</p> <p>1 are legally protected.      2 But with respect to this event and this      3 case, did you follow Mayo procedures in regard      4 to morbidity and mortality in review of the      5 case?</p> <p>6 <b>A. Yeah. The case was presented.</b>      7 Q. Okay. Let's leave it there.</p> <p>8 Are there people at Mayo in charge of      9 compliance and other issues related to reporting      10 of events?</p> <p>11 <b>A. Yes. There's -- there's a whole team</b>      12 <b>in the transplant center for -- to take care of</b>      13 <b>compliance and report what needs to be reported.</b></p> <p>14 Q. And do you rely on those people to      15 determine what needs to be reported and -- and      16 how and when?</p> <p>17 <b>A. Yes.</b>      18 Q. Okay. Do you have any recollection of      19 discussing potential use of -- of OCS with Mr.      20 Leopold or -- and/or his family?</p> <p>21 <b>A. It --</b>      22 <b>I don't recall exactly the 30-minute</b>      23 <b>conversation or so, but it is -- you know, in</b>      24 <b>most of the cases I will tell them what type of</b>      25 <b>procurement we would use, and if it will be the</b></p>	<p style="text-align: right;">Page 128</p> <p>1 <b>far equivalent results, and even equivalent</b>      2 <b>results in more complex cases. So you take</b>      3 <b>cases for farther away, if your recipient needs</b>      4 <b>a more complex operation that would need to, you</b>      5 <b>know, wait a long time, and any -- anything, you</b>      6 <b>know, far away, any technical difficulty or --</b>      7 <b>you know, the OCS have shown equivalent results.</b>      8 <b>Also, other type of donors, like the DCD donors,</b>      9 <b>have shown equivalence to brain dead and cold</b>      10 <b>storage -- versus cold storage heart</b>      11 <b>transplantation.</b>      12 Q. So is this --      13 <b>A. Even in DCD, the most difficult of the</b>      14 <b>donors.</b>      15 Q. Okay. Is this a --      16 So is that something that you're      17 telling patients is more risky, or -- or not?      18 <b>A. No, because it's -- this have</b>      19 <b>demonstrated the same results in more complex</b>      20 <b>situations, so what I have told them that the --</b>      21 <b>the OCS TransMedics help us, you know, to go</b>      22 <b>further and to be, you know, safer in the most</b>      23 <b>complex operations or in the most complex donors</b>      24 <b>like -- like the DCDs and that will have</b>      25 <b>equivalent results. And likely, you know, if</b></p>
<p style="text-align: right;">Page 127</p> <p>1 <b>heart in a box -- I usually refer to the heart</b>      2 <b>in a box -- and if the patient understands</b>      3 <b>what's the heart in a box, then we, you know,</b>      4 <b>tell the other patients. So most of the cases,</b>      5 <b>you know, before I -- we go to transplant, I</b>      6 <b>tell them, but I don't recall the 30-minute</b>      7 <b>conversation from that day.</b>      8 Q. Okay. So am I understanding it      9 correctly that you're saying you don't remember      10 specifically in this case, but in -- in many      11 cases or in most cases you will --</p> <p>12 <b>A. Yeah.</b>      13 Q. -- talk to patients about that?      14 <b>A. Yeah. I'm almost -- probably in the --</b>      15 <b>When I talk to the people in the</b>      16 <b>outpatient setting, in a hundred percent I'm --</b>      17 <b>get sure that I talk to -- to it, and -- and I</b>      18 <b>would say very likely close to a hundred in the</b>      19 <b>inpatient setting.</b>      20 Q. Is there any, in your judgment, in your      21 practice, is there any -- is there any risk      22 concern associated with using OCS under the      23 correct circumstances as compared to cold      24 storage or cold transit?      25 <b>A. Yeah. It is -- it has been shown so</b></p>	<p style="text-align: right;">Page 129</p> <p>1 they get it transplanted quicker, the waiting-      2 list mortality of -- you know, will be decreased      3 because you get access to more organs. Because      4 what you want to avoid is to have -- to avoid      5 waiting-list mortality, which is somebody in      6 cardiogenic shock is a high risk of death, so      7 you want to avoid the waiting-list mortality.      8 Q. Okay. I would like to ask about      9 another topic. Mr. Thompson asked you some      10 questions about OPTN guidance. Do you remember      11 that?      12 <b>A. Yes.</b>      13 Q. And he read to you some language from      14 an OPTN document, but he actually didn't show      15 you the document; did he?      16 <b>A. He didn't.</b>      17 MR. BRANTINGHAM: I'm going to ask to      18 just mark this OPTN document as Exhibit 1.      19 (Exhibit 1 was marked for      20 identification.)      21 BY MR. BRANTINGHAM:      22 Q. If you look on that document, doctor,      23 on the second page there's a header,      24 Recommendations, and then a subheader, Deceased      25 Donor Work Group Recommendations. Do you see</p>

<p style="text-align: right;">Page 130</p> <p>1       that?</p> <p>2       <b>A. Yes.</b></p> <p>3       Q. What does the language after number</p> <p>4       four on that list say?</p> <p>5       <b>A. "The following information should not</b></p> <p>6       <b>be disclosed: Religion; specific diagnosis;</b></p> <p>7       <b>ethnicity and race; sexual orientation; chronic</b></p> <p>8       <b>illness unrelated to the donation; mechanism of</b></p> <p>9       <b>injury or death."</b></p> <p>10      Q. You answered some questions about</p> <p>11     whether you disclosed, I think, to the patient</p> <p>12     here the particular mechanism of this donor's</p> <p>13     death. Does, as far as you know, does this</p> <p>14     guidance apply to that question?</p> <p>15      <b>A. Yes, it does.</b></p> <p>16      Q. And what does it mean?</p> <p>17      <b>A. It means that you cannot disclose that,</b></p> <p>18      <b>because if I disclose it, I might be banned from</b></p> <p>19      <b>my transplant practice.</b></p> <p>20      MR. BRANTINGHAM: I have no further</p> <p>21     questions.</p> <p>22           EXAMINATION</p> <p>23     BY MR. THOMPSON:</p> <p>24      Q. Your testimony is that you think that</p> <p>25     OPTN would ban you from your transplant practice</p>	<p style="text-align: right;">Page 132</p> <p>1       make sure that the recipient and/or their family</p> <p>2       can't track down the donor; right?</p> <p>3       <b>A. Yes.</b></p> <p>4       Q. Right? Explain to me how telling Noah</p> <p>5       Leopold that the donor was coming from a heart</p> <p>6       that had -- person who had died of an</p> <p>7       intracranial hemorrhage could possibly have led</p> <p>8       to them tracking down the donor.</p> <p>9       MR. BRANTINGHAM: I think this has been</p> <p>10      asked and answered.</p> <p>11      MR. THOMPSON: Not of him.</p> <p>12      THE WITNESS: Yeah.</p> <p>13      MR. BRANTINGHAM: Okay.</p> <p>14      MR. THOMPSON: And you brought it up,</p> <p>15      foolishly, but you did.</p> <p>16      MR. BRANTINGHAM: Well hold on a</p> <p>17      second. You're asking him a completely</p> <p>18      different subject here from what's in -- just</p> <p>19      written in that document.</p> <p>20      MR. THOMPSON: No, I'm not at all.</p> <p>21      MR. BRANTINGHAM: Okay. Go ahead. You</p> <p>22      can answer the question.</p> <p>23      <b>A. Well if the --</b></p> <p>24      <b>By word of mouth, the transplant</b></p> <p>25      <b>professional can talk to each other about</b></p>
<p style="text-align: right;">Page 131</p> <p>1       if you told a patient that the donor heart had</p> <p>2       died of an intracranial hemorrhage.</p> <p>3       <b>A. Yes, they can do that.</b></p> <p>4       Q. Yeah. Have you ever heard of that ever</p> <p>5       happening?</p> <p>6       <b>A. Yes. They have closed programs for</b></p> <p>7       <b>poor compliance.</b></p> <p>8       Q. For telling people that somebody died</p> <p>9       of an intracranial hemorrhage?</p> <p>10      <b>A. For -- for poor compliance.</b></p> <p>11      Q. That wasn't my question.</p> <p>12      <b>A. And -- and I'll answer your question.</b></p> <p>13      <b>This goes into -- there's a law, the HIPAA law,</b></p> <p>14      <b>and they have been questioned, they have been</b></p> <p>15      <b>sued and have to pay huge amounts of money for</b></p> <p>16      <b>revealing confidential information and</b></p> <p>17      <b>deceased-donor information.</b></p> <p>18      Q. Okay. Both HIPAA and the OPTN</p> <p>19      Guidelines have to do with protecting donor</p> <p>20      anonymity; right?</p> <p>21      <b>A. Protecting what? Donor --</b></p> <p>22      Q. Donor anonymity.</p> <p>23      <b>A. Yes.</b></p> <p>24      Q. The whole reason that you're not</p> <p>25      supposed to disclose certain information is to</p>	<p style="text-align: right;">Page 133</p> <p>1       <b>confidential information and the recipient can</b></p> <p>2       <b>get to know where -- where is that, so they can</b></p> <p>3       <b>identify them, the donor.</b></p> <p>4       Q. How?</p> <p>5       <b>A. So they -- they can see who died, you</b></p> <p>6       <b>know, in, you know, a period, and then talk to</b></p> <p>7       <b>other people and talk to other people, and</b></p> <p>8       <b>that's the way that things get usually distorted</b></p> <p>9       <b>and that -- do not get it right and they do not</b></p> <p>10       <b>get confidential.</b></p> <p>11       Q. Yeah. We're going to stick, though,</p> <p>12       with the actual purpose of the regulation, and I</p> <p>13       thought you agreed with me, is to make sure that</p> <p>14       the recipient and/or his family can't track down</p> <p>15       the donor; right?</p> <p>16       MR. BRANTINGHAM: Foundation.</p> <p>17       <b>A. No. They -- they --</b></p> <p>18       <b>The information should be confidential.</b></p> <p>19       Q. Confidential in order to keep the</p> <p>20       donor's identity confidential; right?</p> <p>21       <b>A. Yes.</b></p> <p>22       Q. Okay. So back to my question. Explain</p> <p>23       to me how telling Noah Leopold "Your donor heart</p> <p>24       is coming from somebody who died of an</p> <p>25       intracranial hemorrhage" could possibly lead to</p>

<p style="text-align: right;">Page 134</p> <p>1 the donor being identified.</p> <p>2     <b>A. Yeah. From one person to another</b></p> <p>3     <b>can -- the word of mouth, as I already said.</b></p> <p>4     Q. Word of mouth --</p> <p>5     <b>A. And the other -- let me finish -- and</b></p> <p>6     <b>the other thing that can happen, that family can</b></p> <p>7     <b>black -- after they get to know after one year</b></p> <p>8     <b>or more what happened, they can, you know,</b></p> <p>9     <b>blackmail donors or vice versa to say about any</b></p> <p>10     <b>confidential like, you know, this donor, we are</b></p> <p>11     <b>going to let the people know that this human</b></p> <p>12     <b>being, you know, was a drug addict and give --</b></p> <p>13     <b>you know, that information and blackmail people.</b></p> <p>14     So we want to avoid any, you know, extortion</p> <p>15     practices --</p> <p>16     Q. Again, --</p> <p>17     <b>A. -- as well.</b></p> <p>18     Q. -- in order for that to happen, the</p> <p>19     recipient's family would have to know who the</p> <p>20     donor is; right?</p> <p>21     <b>A. Yeah. They can find out.</b></p> <p>22     Q. How? You haven't explained it to me.</p> <p>23     You said word of --</p> <p>24     <b>A. Well I did it. I did --</b></p> <p>25     Q. Hold on. Hold on.</p>	<p style="text-align: right;">Page 136</p> <p>1     MR. THOMPSON: No. Because what he's</p> <p>2     saying is ridiculous. It's patently wrong and</p> <p>3     ridiculous.</p> <p>4     <b>A. No, no, no.</b></p> <p>5     MR. BRANTINGHAM: Hold on. Just hold</p> <p>6     up. Just, doctor, hold up.</p> <p>7     <b>A. No, no, no. I don't --</b></p> <p>8     <b>Listen, --</b></p> <p>9     Q. And I'm going to be incredulous about</p> <p>10     it.</p> <p>11     <b>A. -- I'm not going to accept any insults</b></p> <p>12     <b>from you.</b></p> <p>13     Q. Okay. So stick with my question.</p> <p>14     <b>A. Can you retract your insults?</b></p> <p>15     Q. Stick with my --</p> <p>16     No.</p> <p>17     <b>A. Can you retract your insult?</b></p> <p>18     Q. What you're saying --</p> <p>19     <b>A. Don't insult me.</b></p> <p>20     Q. What you are saying makes no sense to</p> <p>21     me, and so I am trying to figure out what it is</p> <p>22     that you're saying.</p> <p>23     <b>A. Well you have --</b></p> <p>24     MR. BRANTINGHAM: Please let him</p> <p>25     explain.</p>
<p style="text-align: right;">Page 135</p> <p>1     MR. BRANTINGHAM: Let him finish the</p> <p>2     question.</p> <p>3     Q. Let me finish my question.</p> <p>4     You've said "word of mouth." Explain</p> <p>5     to me specifically, word of mouth between who</p> <p>6     and who is somehow going to lead this family in</p> <p>7     Florida to know specifically that this heart</p> <p>8     came from one individual person in Idaho that</p> <p>9     had an intracranial hemorrhage.</p> <p>10     <b>A. Let's -- let's say that there's</b></p> <p>11     <b>friends, that one friend works in Idaho and</b></p> <p>12     <b>other works at the Mayo Clinic --</b></p> <p>13     Q. But they don't know it's coming from</p> <p>14     Idaho.</p> <p>15     <b>A. Well but they know there will be donor</b></p> <p>16     <b>and they will match the time.</b></p> <p>17     Q. How --</p> <p>18     <b>A. Yeah.</b></p> <p>19     Q. Match what times?</p> <p>20     <b>A. Yeah.</b></p> <p>21     Q. What are you talking about?</p> <p>22     MR. BRANTINGHAM: Hold on one second.</p> <p>23     You're -- you're explicitly asking him to</p> <p>24     speculate. Now you're getting upset that he's</p> <p>25     speculating as you're asking him to, I mean --</p>	<p style="text-align: right;">Page 137</p> <p>1     Q. First let me ask the question.</p> <p>2     <b>A. Yeah. I already answered to you.</b></p> <p>3     <b>There could be somebody in the Idaho hospital</b></p> <p>4     <b>that is a friend of somebody as a whole -- at</b></p> <p>5     <b>Mayo that, you know, knows about the donor and</b></p> <p>6     <b>they will -- can be talking to each other, so we</b></p> <p>7     <b>cannot reveal any details of the case. And that</b></p> <p>8     <b>is the way it's mandated and I don't have to</b></p> <p>9     <b>explain it to you any further.</b></p> <p>10     Q. Got it. You realize that even this</p> <p>11     part of the guidance that says cause of death</p> <p>12     should not be given, Mr. Brantingham didn't read</p> <p>13     the rest of that sentence, did he, where it says</p> <p>14     "unless the information is clinically relevant</p> <p>15     to the transplant recipient informed consent</p> <p>16     discussion." Do you see that part that Mr.</p> <p>17     Brantingham left out?</p> <p>18     MR. BRANTINGHAM: I didn't actually</p> <p>19     read any of it. I had the witness read it,</p> <p>20     but --</p> <p>21     Q. Oh, you left it out then.</p> <p>22     <b>A. I -- I read that, so all the relevant</b></p> <p>23     <b>information was disclosed to Mr. Noah.</b></p> <p>24     MR. BRANTINGHAM: And what's -- what's</p> <p>25     the language you're talking about? Because he</p>

<p style="text-align: right;">Page 138</p> <p>1 read number four.</p> <p>2 MR. THOMPSON: Right -- right. No.</p> <p>3 "specific age or circumstance of death..."</p> <p>4 Oh, you had him read number four?</p> <p>5 MR. BRANTINGHAM: Yeah. That's when</p> <p>6 you put the document in front of the witness.</p> <p>7 Q. It's --</p> <p>8 Isn't this also --</p> <p>9 MR. THOMPSON: Stop. Stop.</p> <p>10 Q. Are you telling me that you think that</p> <p>11 number four here overrules your legal obligation</p> <p>12 to provide informed consent to your patients?</p> <p>13 <b>A. I do prefer --</b></p> <p>14 <b>I do provide informed consent.</b></p> <p>15 Q. Wasn't my question.</p> <p>16 <b>A. I don't know. I don't know.</b></p> <p>17 Q. Okay.</p> <p>18 <b>A. I -- I provide informed consent to the</b> <b>patient. All the thing that you can do is</b> <b>speculation.</b></p> <p>19 Q. All right. Let's do some more talk</p> <p>20 about informed consent.</p> <p>21 You told Mr. Brantingham now after the</p> <p>22 break that hundred percent of the time, when you</p> <p>23 talk to a patient in an outpatient setting, you</p>	<p style="text-align: right;">Page 140</p> <p>1 <b>transplantation with the OCS device. So I talk</b> <b>to each one, it will be completely irrelevant.</b></p> <p>2 Q. Did you know that your friends at</p> <p>3 TransMedics specifically say physicians and</p> <p>4 patients should be aware of the results of the</p> <p>5 PROCEED trial?</p> <p>6 MR. BRANTINGHAM: Object to the form of</p> <p>7 the question.</p> <p>8 <b>A. Yeah.</b></p> <p>9 Q. Do you see that?</p> <p>10 <b>A. All right. I -- I haven't read this.</b></p> <p>11 Q. Okay.</p> <p>12 <b>A. I --</b></p> <p>13 Q. So this is --</p> <p>14 <b>A. But -- but --</b></p> <p>15 MR. BRANTINGHAM: Just let him -- let</p> <p>16 him ask a question.</p> <p>17 <b>A. You ask me something. So but as, you</b> <b>know, I told you the answer that the study was</b> <b>equivalent, the PROCEED II trial says that it's</b> <b>equivalent.</b></p> <p>18 Q. Okay.</p> <p>19 <b>A. So I, indirectly, I -- I tell them.</b></p> <p>20 Q. Great. So now I'll ask you a different</p> <p>21 question.</p>
<p style="text-align: right;">Page 139</p> <p>1 talk to them about the heart in a box.</p> <p>2 <b>A. Yes, sir.</b></p> <p>3 Q. Okay. What do you tell them?</p> <p>4 <b>A. That there's, you know, different ways</b> <b>of preserving the heart; one is cold storage</b> <b>that allows four hours, and then we have OCS,</b> <b>you know, the heart in a box, that give us at</b> <b>least eight hours, but we don't know actually</b> <b>how long, and that's it.</b></p> <p>5 Q. You don't tell them anything else.</p> <p>6 <b>A. It's a -- it's --</b></p> <p>7 <b>That it's a good tool that is</b> <b>equivalent to cold storage.</b></p> <p>8 Q. Do you tell them about the results of</p> <p>9 the PROCEED trial?</p> <p>10 <b>A. Not as specifically.</b></p> <p>11 Q. Why not?</p> <p>12 <b>A. Because if I have -- start talking</b> <b>about all the trials, you know, I'll finish, you</b> <b>know, in several years.</b></p> <p>13 Q. I'm not talking about all the trials.</p> <p>14 I'm just talking about one trial.</p> <p>15 <b>A. Well this --</b></p> <p>16 <b>I mean if you see the literature,</b> <b>there's around 20 studies on heart</b></p>	<p style="text-align: right;">Page 141</p> <p>1 <b>A. But I do not ask about the PROCEED.</b></p> <p>2 Q. Right.</p> <p>3 <b>A. That would be completely irrelevant.</b></p> <p>4 Q. Do you tell your patients that in the</p> <p>5 PROCEED trial overall survival was lower for OCS</p> <p>6 patients than in patients who were given hearts</p> <p>7 preserved with cold static preservation?</p> <p>8 <b>A. That's wrong. It's not significant.</b></p> <p>9 Q. What's that?</p> <p>10 <b>A. That's wrong. It's not significant.</b></p> <p>11 Q. Wrong and not significant.</p> <p>12 Are you going to tell your friends at</p> <p>13 TransMedics that they should edit that part of</p> <p>14 their user manual that says physicians and</p> <p>15 patients should know about that?</p> <p>16 MR. BRANTINGHAM: Object to the form.</p> <p>17 Q. Go ahead and read it. I'm putting it</p> <p>18 in front of you like Mr. Brantingham wants me</p> <p>19 to. Read that bullet point to yourself. Read</p> <p>20 that whole thing and tell me when you're done.</p> <p>21 <b>A. (Witness complying.)</b></p> <p>22 <b>Well when I --</b></p> <p>23 Q. Just --</p> <p>24 Sorry. I told you to read it and tell</p> <p>25 me when you're done. Are you done?</p>

<p style="text-align: right;">Page 142</p> <p>1       <b>A. Yeah, I'm done.</b>      2       Q. Do you comply with that?      3       <b>A. They are not my governing tool,</b>      4       <b>TransMedics.</b>      5       Q. So is your answer "No, I do not comply      6       with that?"      7       <b>A. They -- I'm --</b>      8       <b>I do not have compliance issues with</b>      9       <b>TransMedics, so I -- I -- there's no compliance</b>      10      <b>with TransMedics.</b>      11      Q. Do you do --      12      <b>A. I'm a customer.</b>      13      Q. Do you do what this part of the manual      14      tells you to do?      15      <b>A. Indirectly, yes.</b>      16      Q. How?      17      <b>A. When I said that it's around the same</b>      18      <b>results.</b>      19      Q. Right. You tell them something that's      20      completely different and contradictory to what      21      this tells you to tell them.      22      <b>A. Well -- well you could read the whole</b>      23      <b>article and you will see that there's no</b>      24      <b>significant difference.</b>      25      Q. Okay. Listen to my question, please.</p>	<p style="text-align: right;">Page 144</p> <p>1       <b>A. (Witness shaking head.)</b>      2       Q. Your answer?      3       <b>A. No, they are not a governing body. I</b>      4       <b>do not do what their website says.</b>      5       Q. Okay. This came off the FDA website --      6       <b>A. Uh-huh.</b>      7       Q. -- for your information.      8       <b>A. Okay.</b>      9       Q. So you don't do what the FDA website      10      says.      11      <b>A. Yeah.</b>      12      MR. BRANTINGHAM: Well foundation and      13      form.      14      Q. Well I can bring it up on the computer,      15      but --      16      <b>A. No. You told me that it was a</b>      17      <b>TransMedics sign.</b>      18      Q. No. I told you it's the TransMedics      19      manual --      20      <b>A. Well then --</b>      21      Q. Hold on.      22      <b>A. All right.</b>      23      Q. We can't talk over one another.      24      <b>A. Yeah. You should follow that advice to</b>      25      <b>yourself.</b></p>
<p style="text-align: right;">Page 143</p> <p>1       Is it your testimony --      2       <b>A. Listen to my answer.</b>      3       Q. Is it your testimony that when you      4      advise patients about the OCS, you actually tell      5      them something contrary to what the manufacturer      6      advises you to tell them?      7       <b>A. Well it's not contrary. It is that</b>      8       <b>the -- it's lower, but it's not significant, so</b>      9       <b>it needs more elaboration there to get the --</b>      10      <b>the fact to be truth. So it's not</b>      11      <b>contradictory.</b>      12      Q. When you meet with patients and tell      13      them about the heart in the box, do you provide      14      them with the OCS Heart System Patient Brochure?      15      <b>A. No. I'm not --</b>      16      Q. Do you --      17      <b>A. -- not a representative of the company.</b>      18      Q. Do you provide your patients with any      19      written materials?      20      <b>A. Probably the transplant coordinators,</b>      21      <b>but I do not.</b>      22      Q. Got it.      23      So "Patients should review the OCS      24      Heart System Patient Brochure," you don't comply      25      with that part either; do you?</p>	<p style="text-align: right;">Page 145</p> <p>1       MR. BRANTINGHAM: Please go ahead and      2      let's have a question. And just let him --      3       MR. THOMPSON: We do have a question.      4       MR. BRANTINGHAM: -- finish, doctor,      5      and then let's have an answer.      6       Q. Go ahead and just read that to yourself      7      and tell me when you're done.      8       <b>A. (Witness complying.)</b>      9       <b>I'm done.</b>      10      Q. You don't do that either; do you?      11      <b>A. No.</b>      12      Q. And the reason you don't do these      13      things is because you're not governed by      14      TransMedics; right?      15      <b>A. I'm not governed by TransMedics, nope.</b>      16      Q. TransMedics is good enough to pay for      17      you to stay at the Ritz-Carlton in Saint Thomas,      18      but not good enough to give you information      19      about their own device to pass along to your      20      patients.      21      MR. BRANTINGHAM: Hang on. I'll object      22      to the form and the argumentative nature of the      23      question. You can answer.      24      <b>A. I went to investigators meeting in</b>      25      <b>TransMedics. I'm interested in academic work</b></p>

<p style="text-align: right;">Page 146</p> <p>1     <b>and to provide life-saving, cutting-edge therapy</b>  2     <b>to the patients. Other than that, there's no</b>  3     <b>conflict of interest.</b></p> <p>4     Q. Do you think TransMedics is a good  5     company?</p> <p>6     <b>A. They have produced a device that have</b>  7     <b>resulted in increasing -- in increasing heart</b>  8     <b>transplants and increasing, you know,</b>  9     <b>life-saving procedures. In that sense, they are</b>  10     <b>a good company.</b></p> <p>11     Q. Do you think that the device is a good  12     device?</p> <p>13     <b>A. Yes, that's why I use it.</b></p> <p>14     Q. Do you think it is a well-designed  15     device?</p> <p>16     <b>A. Yes, I think it is well designed.</b></p> <p>17     Q. So TransMedics has put out a  18     well-designed, good device that you use for your  19     patients all the time; right?</p> <p>20     <b>A. That is approved by the FDA.</b></p> <p>21     Q. That's approved by the FDA as well.  22         Their manual is also approved by the  23     FDA; is it not?</p> <p>24     MR. BRANTINGHAM: Foundation.</p> <p>25     Q. If you know.</p>	<p style="text-align: right;">Page 148</p> <p>1     Q. Were there other Mayo folks from your  2     department who were at the meeting?</p> <p>3     <b>A. I remember Dr. Spencer was there.</b></p> <p>4     Q. Uh-huh.</p> <p>5     <b>A. From lung transplant, Dr. Saddoughi.</b></p> <p>6     Q. Do you know if this directive that you  7     gave to the people who wanted to do the case  8     report to keep this whole thing under wraps went  9     to Dr. Knop as well?</p> <p>10     MR. BRANTINGHAM: Object to the form of  11     the question.</p> <p>12     <b>A. That was -- that was not the directive.</b></p> <p>13     Q. The directive was "We're not going to  14     publish anything about this outside of Mayo  15     until the lawsuit's over."</p> <p>16     MR. BRANTINGHAM: Object to form. You  17     can answer.</p> <p>18     <b>A. Yeah. Let's -- let's wait.</b></p> <p>19     Q. Okay. So the directive to not talk  20     about this outside of Mayo until the lawsuit's  21     resolved, was that passed on to Dr. Knop as far  22     as you know?</p> <p>23     <b>A. I don't know about that. I remember</b>  24     <b>he --</b></p> <p>25     <b>I don't remember him doing the case-</b></p>
<p style="text-align: right;">Page 147</p> <p>1     <b>A. If you tell me, I can't -- I have no</b>  2     <b>reason not to believe you.</b></p> <p>3     Q. When you were at this meeting in  4     Prague, were you there with Dr. Knop?</p> <p>5     <b>A. I don't remember if he went or not.</b></p> <p>6     Q. I will tell you that he testified under  7     oath this morning that he attended the  8     International Society of Heart and Lung  9     Transplantation meeting in Prague. That's the  10     same meeting that you were talking about when  11     somebody from TransMedics came up to you and  12     said some lawyer's been sniffing around; right?</p> <p>13     MR. BRANTINGHAM: Object to form.</p> <p>14     <b>A. Well again, I don't have any reason not</b>  15     <b>to believe you. You're making a statement. I</b>  16     <b>have no reason not to believe you that Knop --</b>  17     <b>Dr. Knop went to Prague to the IHLT meeting.</b></p> <p>18     Q. Dr. Knop testified that during one of  19     the question-and-answer sessions he got up and  20     he actually provided information about what  21     happened in this case. Did you know that?</p> <p>22     <b>A. I didn't know that.</b></p> <p>23     Q. So you must not have been at that  24     question-and-answer session.</p> <p>25     <b>A. Not that I remember.</b></p>	<p style="text-align: right;">Page 149</p> <p>1     <b>report work. I remember the transplant fellow</b>  2     <b>and a guy from intensive care that I don't</b>  3     <b>remember his name, but I don't know anything</b>  4     <b>about Dr. Knop.</b></p> <p>5     Q. And you told me --</p> <p>6     <b>A. In terms of case reports.</b></p> <p>7     Q. Do you remember the name of the  8     transplant fellow?</p> <p>9     <b>A. Yeah, actually. Chauhan.</b></p> <p>10     Q. Spell that for us, please.</p> <p>11     <b>A. A-k-s-h-a-i space C-h-a-u-h-a-n.</b></p> <p>12     Q. Is that a he or a she?</p> <p>13     <b>A. He.</b></p> <p>14     Q. Is he still here at Mayo?</p> <p>15     <b>A. No. He finished his transplant</b>  16     <b>fellowship.</b></p> <p>17     MR. BRANTINGHAM: It's the one in the  18     medical record that you've asked about.</p> <p>19     MR. THOMPSON: That's the one that  20     we're -- yep. Got it.</p> <p>21     Q. The cardiology person who wanted to do  22     a case report, do you remember his or her name?</p> <p>23     <b>A. No. They are -- you --</b></p> <p>24     <b>Intensive care I think is most likely,</b>  25     <b>not cardiology, intensive care fellow. I</b></p>



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